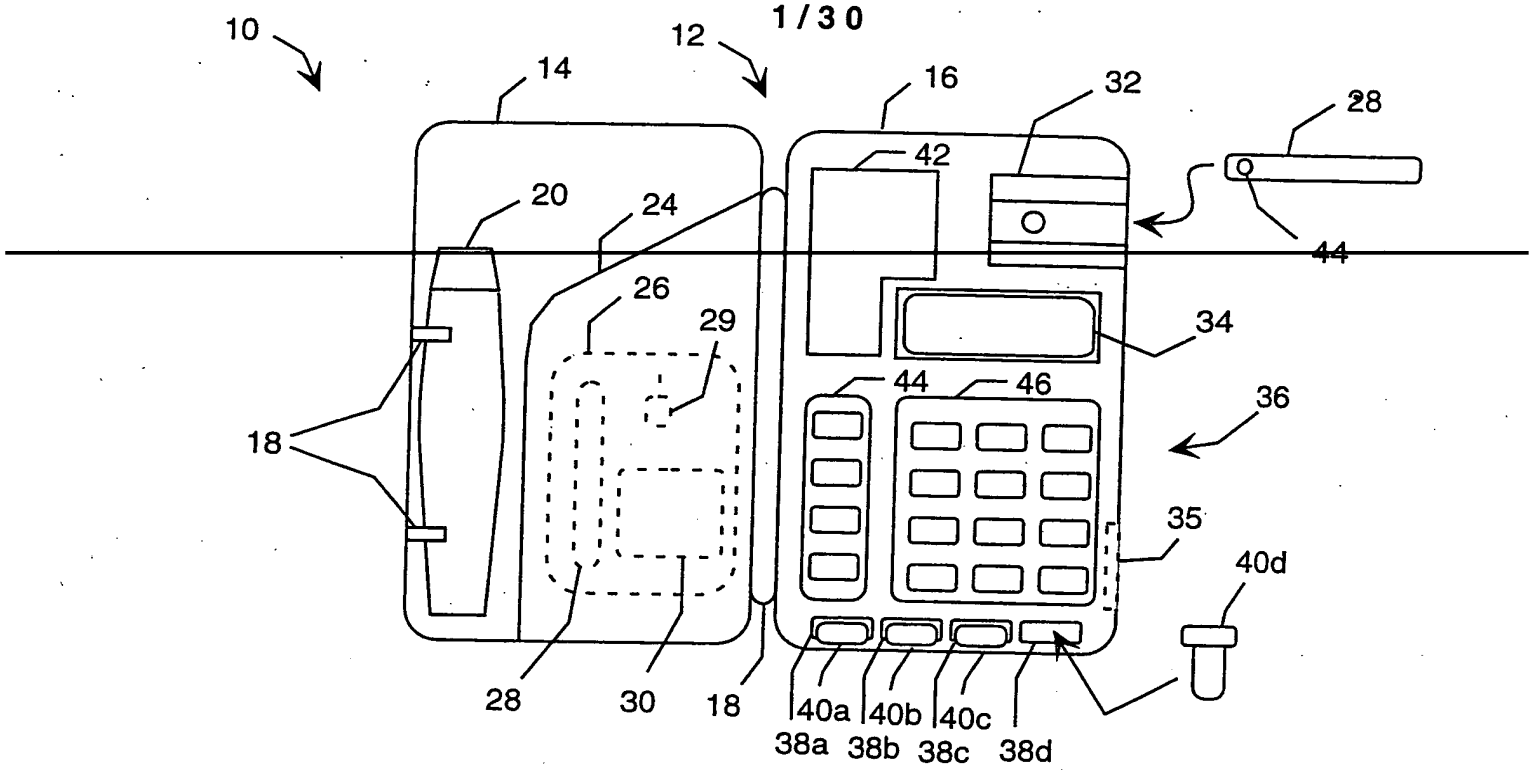

10
12
14
16
32
28
42
20
24
44
26
29
34
44
46
36
18
35
40d
28
30
18
40a
40b
40c
38a
38b
38c
38d

FIG. 1A

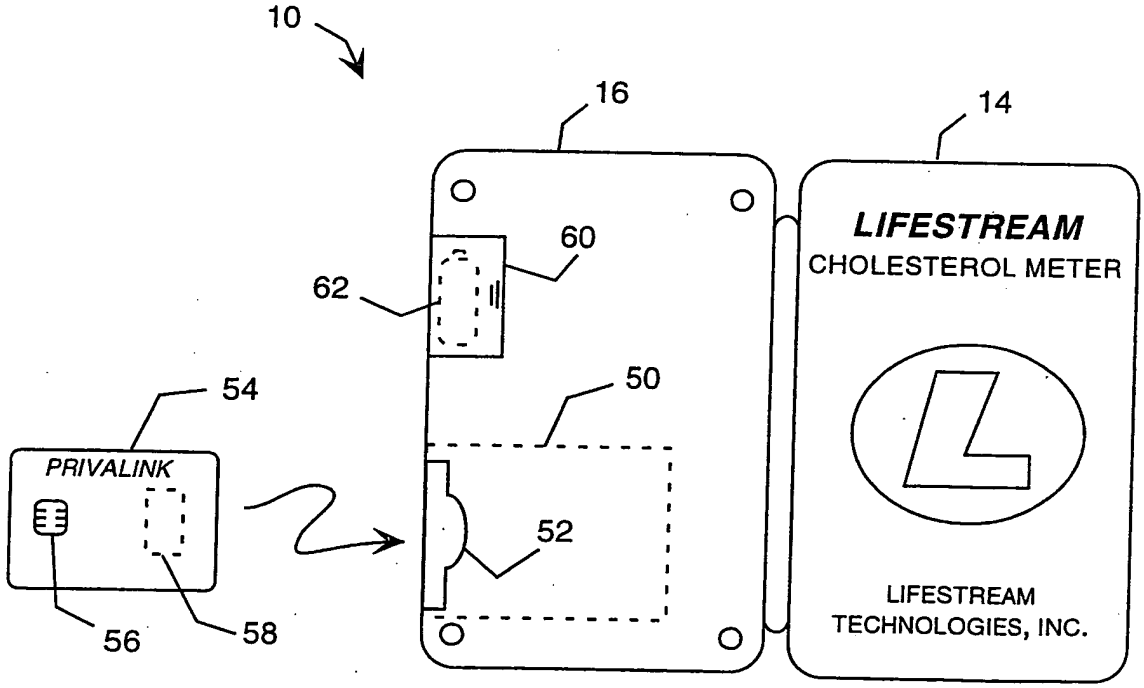

10
16
14
60
62
LIFESTREAM
CHOLESTEROL METER
54
50
PRIVALINK
52
LIFESTREAM
TECHNOLOGIES, INC.
56
58

FIG. 1B

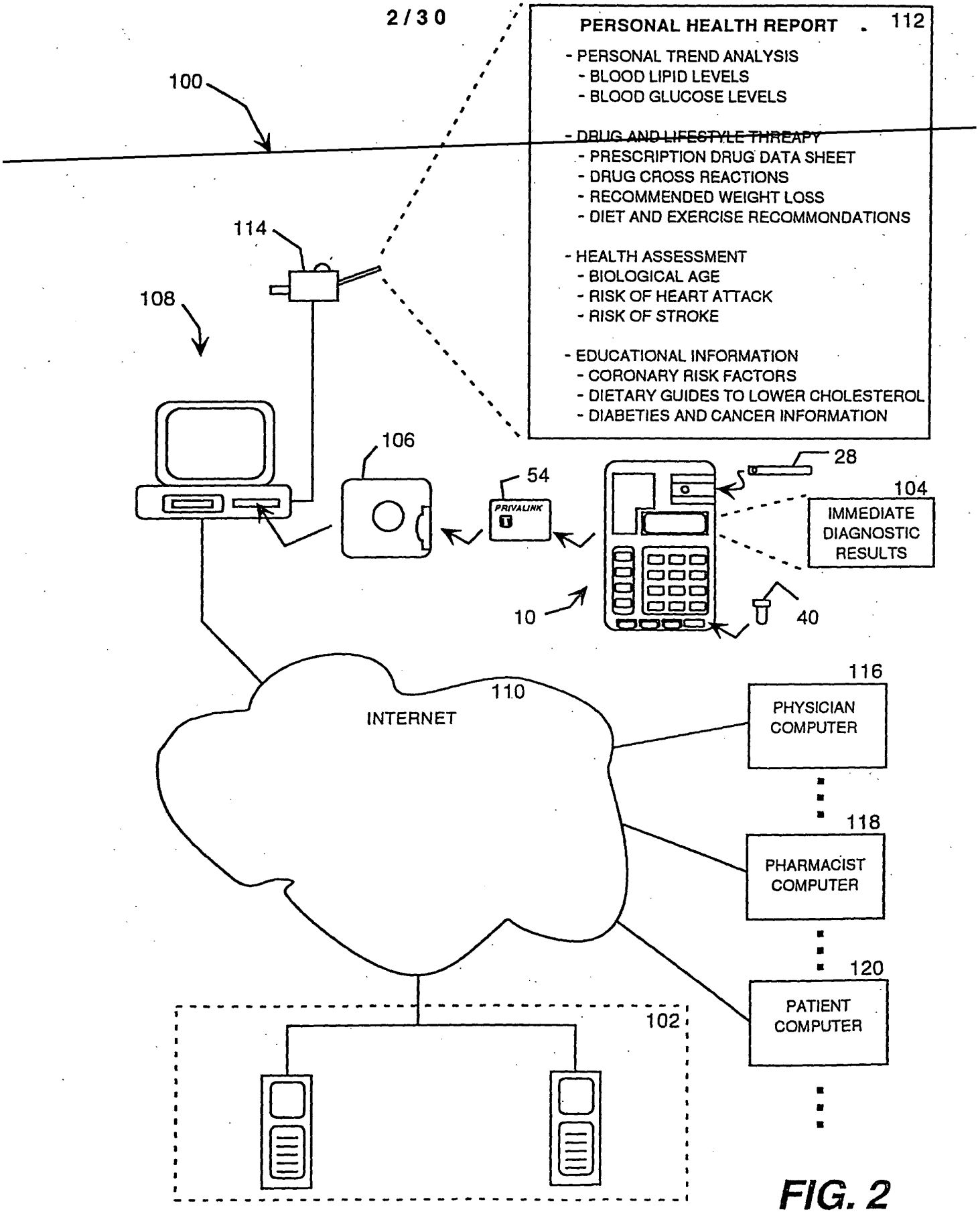

PERSONAL HEALTH REPORT
112
- PERSONAL TREND ANALYSIS
- BLOOD LIPID LEVELS
- BLOOD GLUCOSE LEVELS
- DRUG AND LIFESTYLE THREAPY
- PRESCRIPTION DRUG DATA SHEET
- DRUG CROSS REACTIONS
- RECOMMENDED WEIGHT LOSS
- DIET AND EXERCISE RECOMMONDATIONS
- HEALTH ASSESSMENT
- BIOLOGICAL AGE
- RISK OF HEART ATTACK
- RISK OF STROKE
- EDUCATIONAL INFORMATION
- CORONARY RISK FACTORS
- DIETARY GUIDES TO LOWER CHOLESTEROL
- DIABETIES AND CANCER INFORMATION
100
114
108
106
54
PRIVALINK
28
104
IMMEDIATE DIAGNOSTIC RESULTS
10
40
INTERNET
110
116
PHYSICIAN COMPUTER
118
PHARMACIST COMPUTER
120
PATIENT COMPUTER
102

FIG. 2

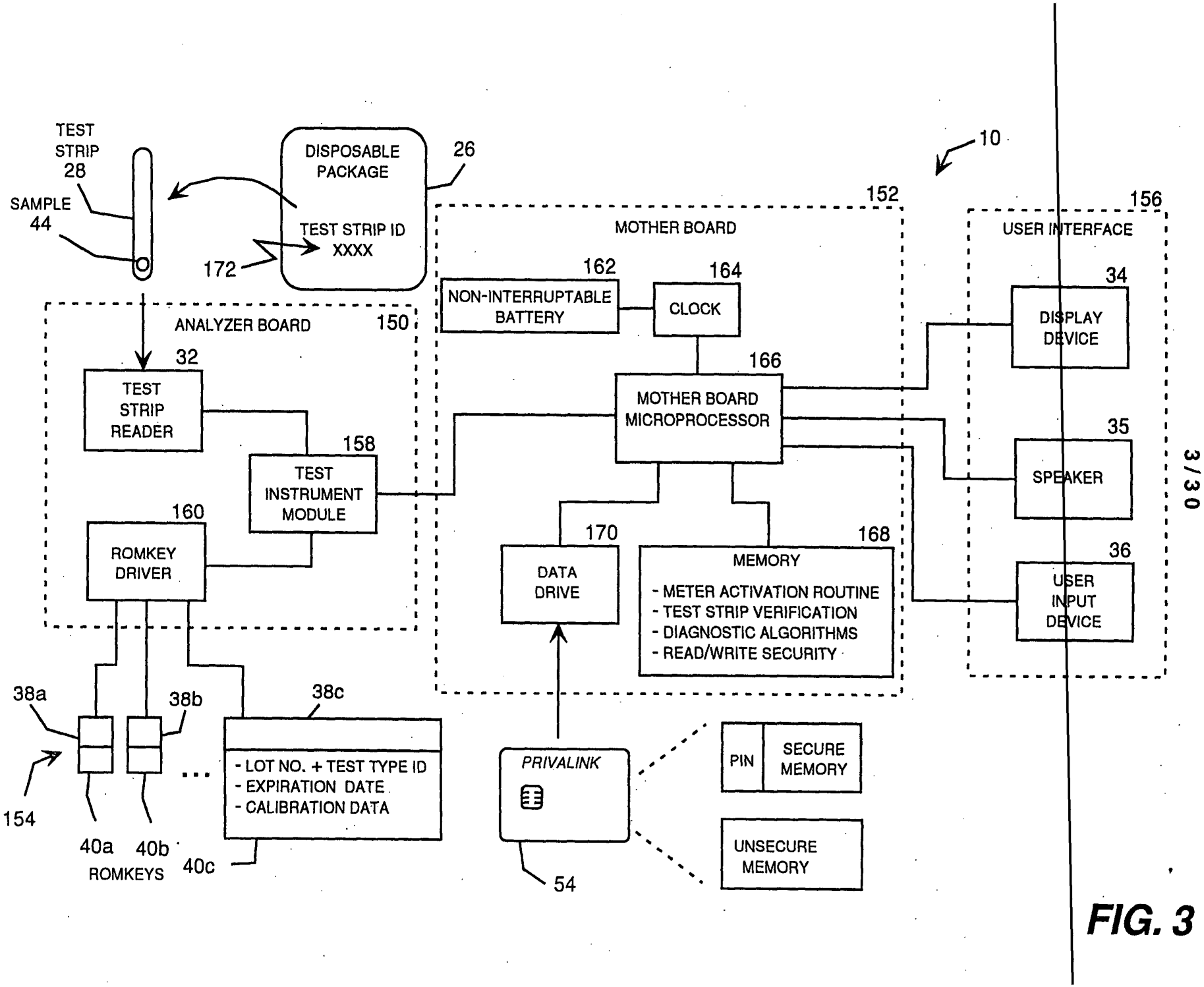

TEST STRIP 28
SAMPLE 44
DISPOSABLE PACKAGE
26
TEST STRIP ID XXXX
172
10
152
MOTHER BOARD
156
USER INTERFACE
162
NON-INTERRUPTABLE BATTERY
164
CLOCK
34
DISPLAY DEVICE
ANALYZER BOARD
150
32
TEST STRIP READER
166
MOTHER BOARD MICROPROCESSOR
158
TEST INSTRUMENT MODULE
35
SPEAKER
160
ROMKEY DRIVER
170
DATA DRIVE
168
MEMORY
- METER ACTIVATION ROUTINE
- TEST STRIP VERIFICATION
- DIAGNOSTIC ALGORITHMS
- READ/WRITE SECURITY
36
USER INPUT DEVICE
38a
38b
38c
- LOT NO. + TEST TYPE ID
- EXPIRATION DATE
- CALIBRATION DATA
PRIVALINK
PIN
SECURE MEMORY
UNSECURE MEMORY
154
40a
40b
ROMKEYS
40c
54

FIG. 3

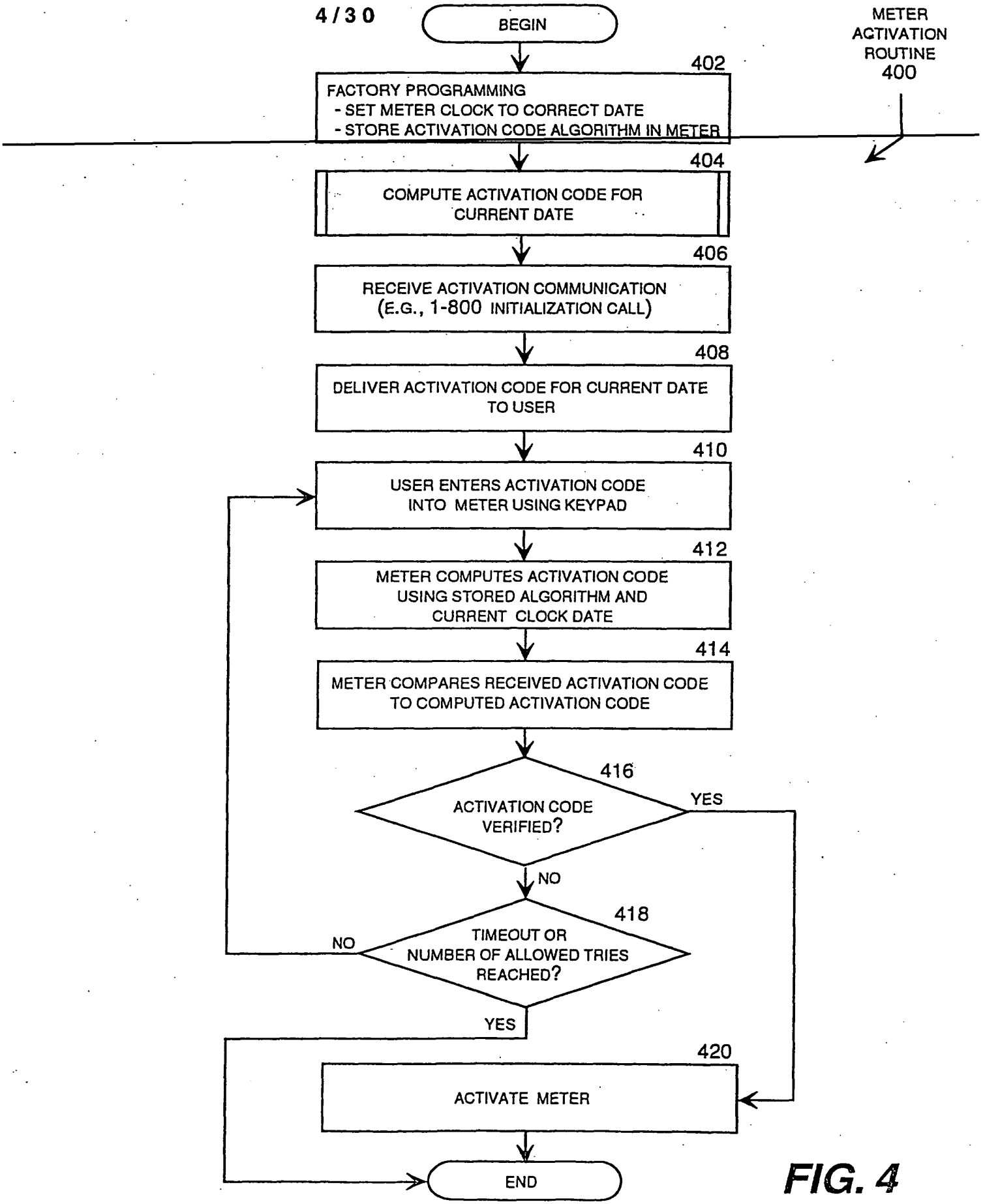

METER ACTIVATION ROUTINE 400
BEGIN
402
FACTORY PROGRAMMING
- SET METER CLOCK TO CORRECT DATE
- STORE ACTIVATION CODE ALGORITHM IN METER
404
COMPUTE ACTIVATION CODE FOR CURRENT DATE
406
RECEIVE ACTIVATION COMMUNICATION (E.G., 1-800 INITIALIZATION CALL)
408
DELIVER ACTIVATION CODE FOR CURRENT DATE TO USER
410
USER ENTERS ACTIVATION CODE INTO METER USING KEYPAD
412
METER COMPUTES ACTIVATION CODE USING STORED ALGORITHM AND CURRENT CLOCK DATE
414
METER COMPARES RECEIVED ACTIVATION CODE TO COMPUTED ACTIVATION CODE
416
ACTIVATION CODE VERIFIED?
YES
NO
418
TIMEOUT OR NUMBER OF ALLOWED TRIES REACHED?
NO
YES
420
ACTIVATE METER
END

FIG. 4

COMPUTE ACTIVATION CODE ROUTINE 404

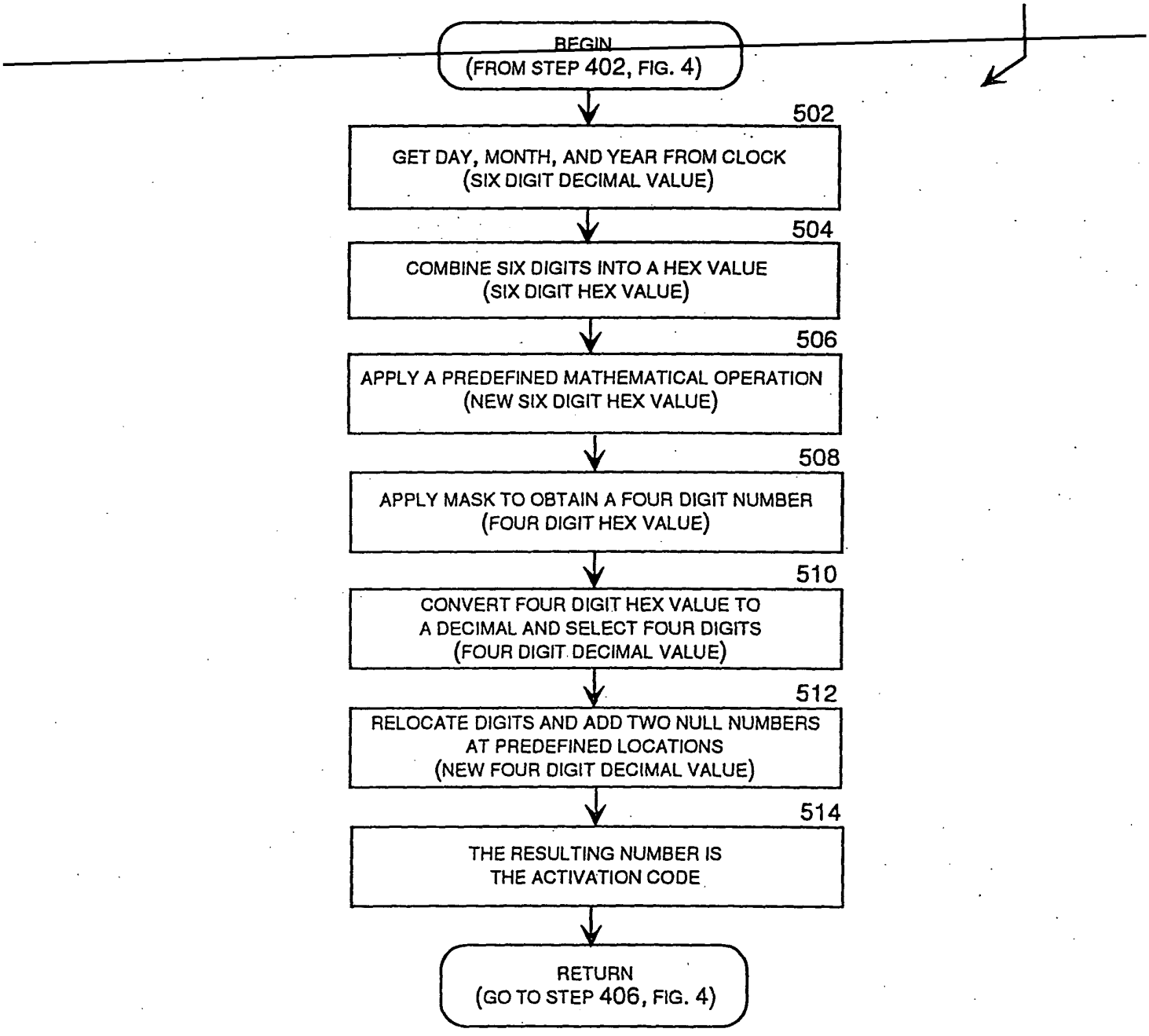
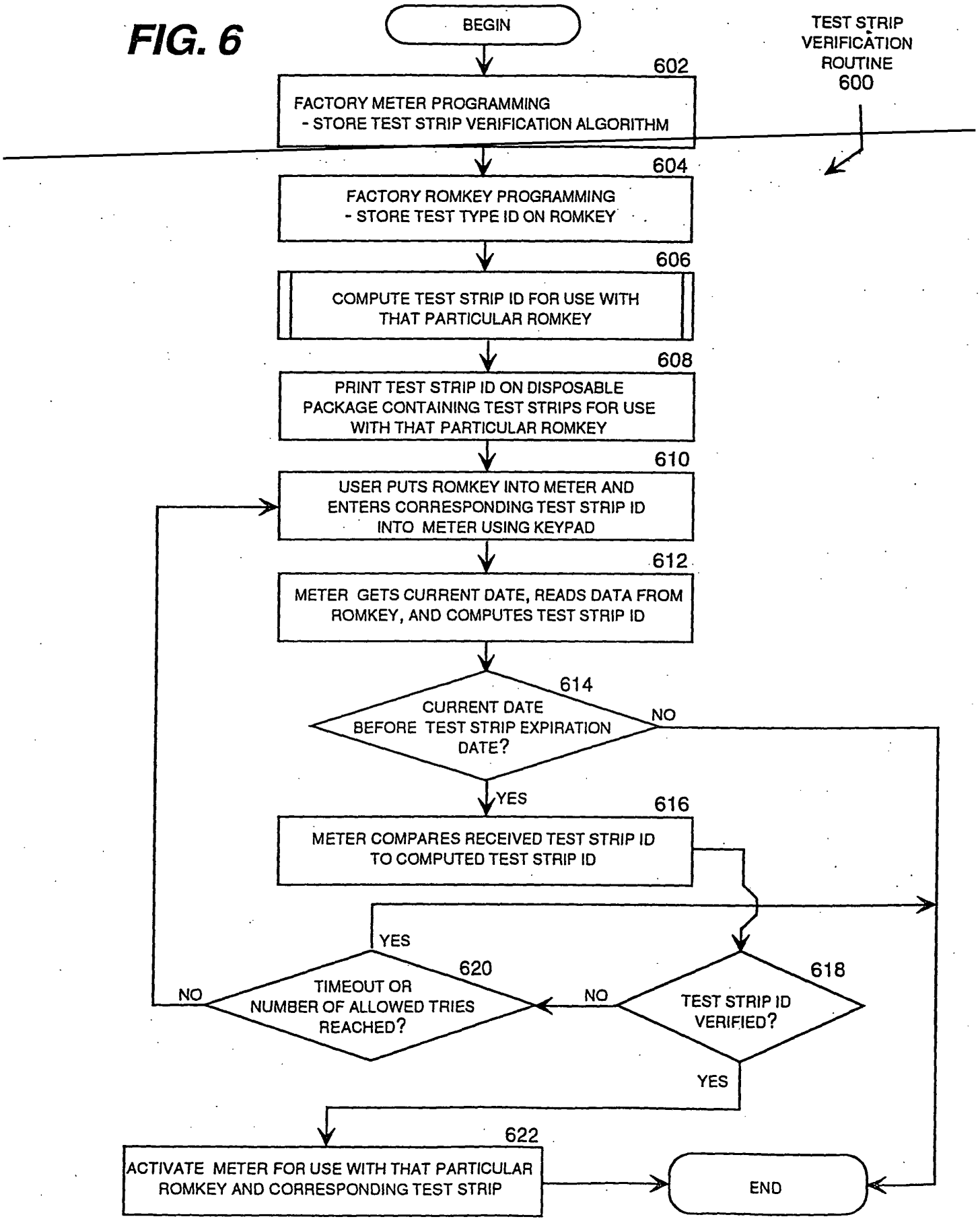


FIG. 5

FIG. 6


BEGIN
602
FACTORY METER PROGRAMMING
- STORE TEST STRIP VERIFICATION ALGORITHM
TEST STRIP VERIFICATION ROUTINE 600
604
FACTORY ROMKEY PROGRAMMING
- STORE TEST TYPE ID ON ROMKEY
606
COMPUTE TEST STRIP ID FOR USE WITH THAT PARTICULAR ROMKEY
608
PRINT TEST STRIP ID ON DISPOSABLE PACKAGE CONTAINING TEST STRIPS FOR USE WITH THAT PARTICULAR ROMKEY
610
USER PUTS ROMKEY INTO METER AND ENTERS CORRESPONDING TEST STRIP ID INTO METER USING KEYPAD
612
METER GETS CURRENT DATE, READS DATA FROM ROMKEY, AND COMPUTES TEST STRIP ID
614
CURRENT DATE BEFORE TEST STRIP EXPIRATION DATE?
NO
YES
616
METER COMPARES RECEIVED TEST STRIP ID TO COMPUTED TEST STRIP ID
YES
620
TIMEOUT OR NUMBER OF ALLOWED TRIES REACHED?
NO
NO
618
TEST STRIP ID VERIFIED?
YES
622
ACTIVATE METER FOR USE WITH THAT PARTICULAR ROMKEY AND CORRESPONDING TEST STRIP
END

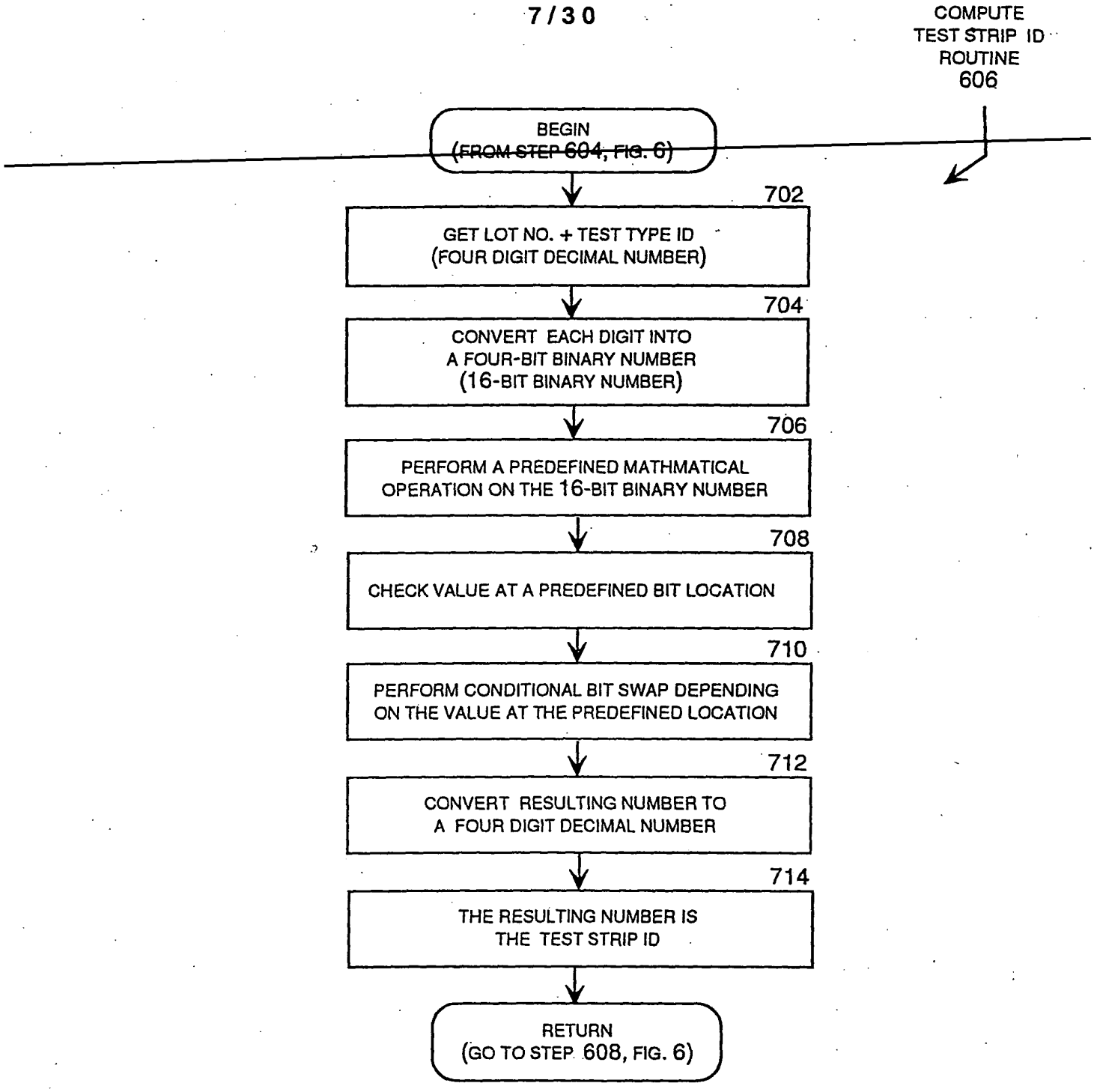

COMPUTE
TEST STRIP ID
ROUTINE
606
BEGIN
(FROM STEP 604, FIG. 6)
702
GET LOT NO. + TEST TYPE ID
(FOUR DIGIT DECIMAL NUMBER)
704
CONVERT EACH DIGIT INTO
A FOUR-BIT BINARY NUMBER
(16-BIT BINARY NUMBER)
706
PERFORM A PREDEFINED MATHMATICAL
OPERATION ON THE 16-BIT BINARY NUMBER
708
CHECK VALUE AT A PREDEFINED BIT LOCATION
710
PERFORM CONDITIONAL BIT SWAP DEPENDING
ON THE VALUE AT THE PREDEFINED LOCATION
712
CONVERT RESULTING NUMBER TO
A FOUR DIGIT DECIMAL NUMBER
714
THE RESULTING NUMBER IS
THE TEST STRIP ID
RETURN
(GO TO STEP 608, FIG. 6)

FIG. 7

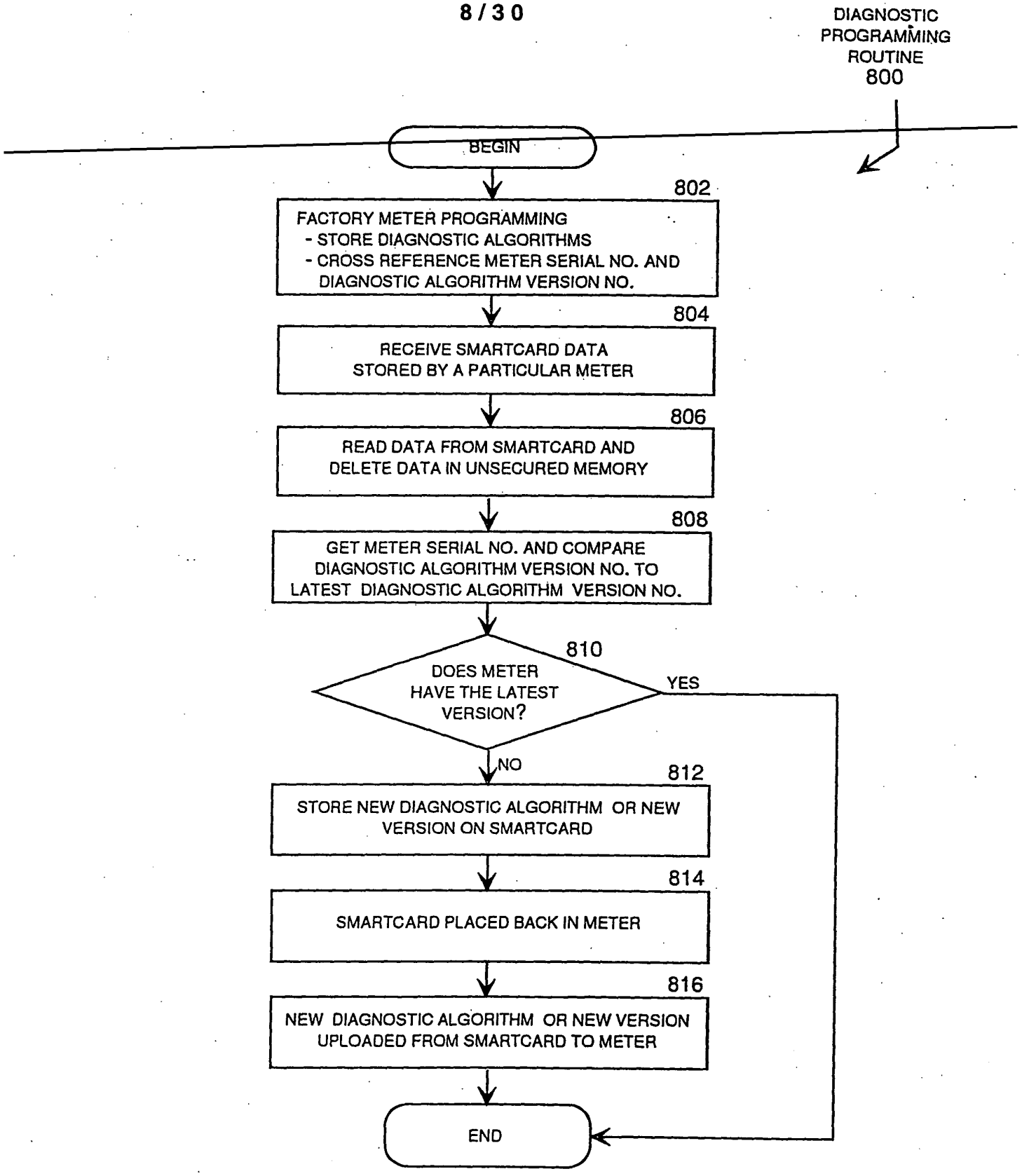

DIAGNOSTIC PROGRAMMING ROUTINE 800
BEGIN
802
FACTORY METER PROGRAMMING
- STORE DIAGNOSTIC ALGORITHMS
- CROSS REFERENCE METER SERIAL NO. AND DIAGNOSTIC ALGORITHM VERSION NO.
804
RECEIVE SMARTCARD DATA STORED BY A PARTICULAR METER
806
READ DATA FROM SMARTCARD AND DELETE DATA IN UNSECURED MEMORY
808
GET METER SERIAL NO. AND COMPARE DIAGNOSTIC ALGORITHM VERSION NO. TO LATEST DIAGNOSTIC ALGORITHM VERSION NO.
810
DOES METER HAVE THE LATEST VERSION?
YES
NO
812
STORE NEW DIAGNOSTIC ALGORITHM OR NEW VERSION ON SMARTCARD
814
SMARTCARD PLACED BACK IN METER
816
NEW DIAGNOSTIC ALGORITHM OR NEW VERSION UPLOADED FROM SMARTCARD TO METER
END

FIG. 8

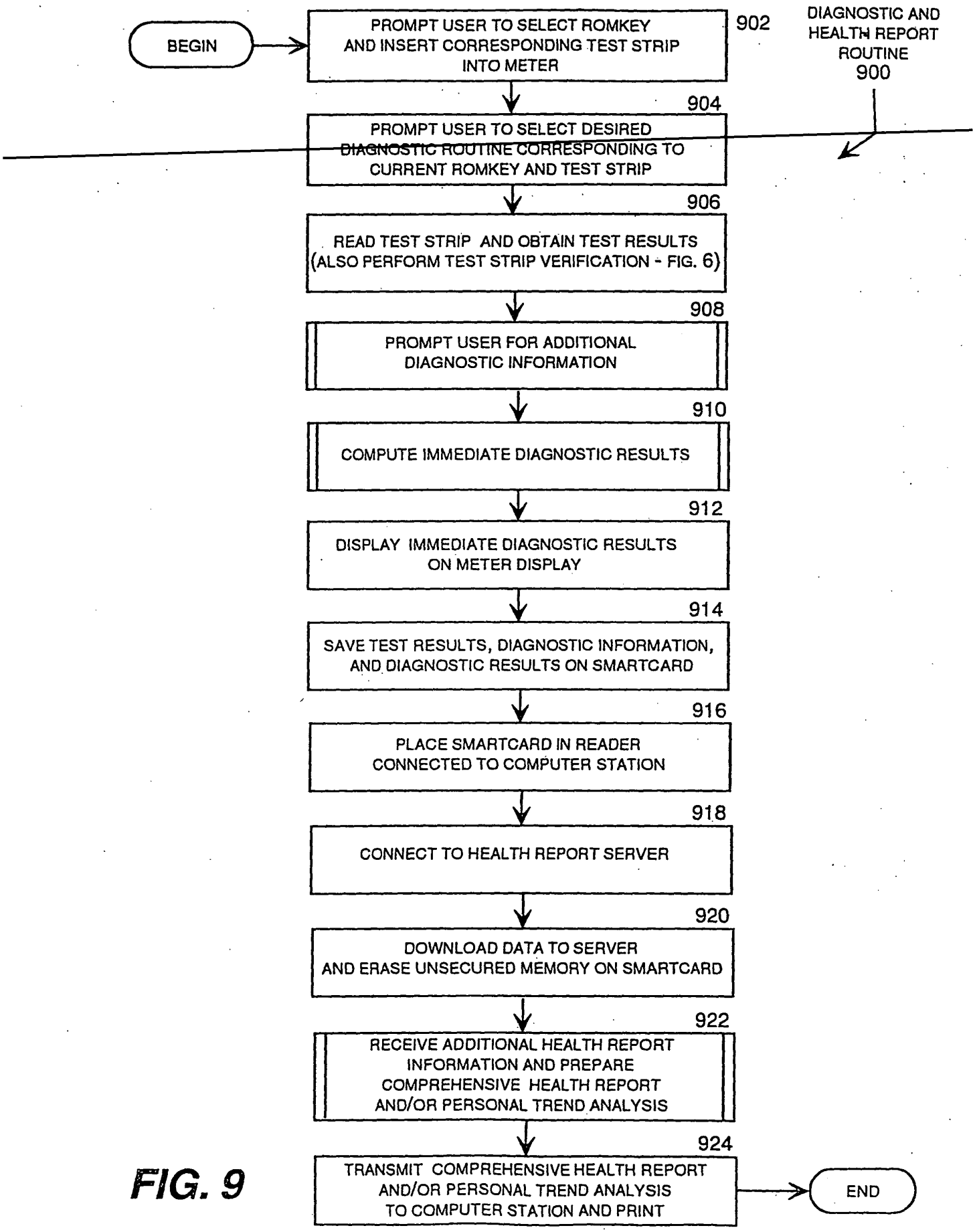

BEGIN
PROMPT USER TO SELECT ROMKEY AND INSERT CORRESPONDING TEST STRIP INTO METER
902
DIAGNOSTIC AND HEALTH REPORT ROUTINE 900
904
PROMPT USER TO SELECT DESIRED DIAGNOSTIC ROUTINE CORRESPONDING TO CURRENT ROMKEY AND TEST STRIP
906
READ TEST STRIP AND OBTAIN TEST RESULTS (ALSO PERFORM TEST STRIP VERIFICATION - FIG. 6)
908
PROMPT USER FOR ADDITIONAL DIAGNOSTIC INFORMATION
910
COMPUTE IMMEDIATE DIAGNOSTIC RESULTS
912
DISPLAY IMMEDIATE DIAGNOSTIC RESULTS ON METER DISPLAY
914
SAVE TEST RESULTS, DIAGNOSTIC INFORMATION, AND DIAGNOSTIC RESULTS ON SMARTCARD
916
PLACE SMARTCARD IN READER CONNECTED TO COMPUTER STATION
918
CONNECT TO HEALTH REPORT SERVER
920
DOWNLOAD DATA TO SERVER AND ERASE UNSECURED MEMORY ON SMARTCARD
922
RECEIVE ADDITIONAL HEALTH REPORT INFORMATION AND PREPARE COMPREHENSIVE HEALTH REPORT AND/OR PERSONAL TREND ANALYSIS
924
TRANSMIT COMPREHENSIVE HEALTH REPORT AND/OR PERSONAL TREND ANALYSIS TO COMPUTER STATION AND PRINT
END

FIG. 9

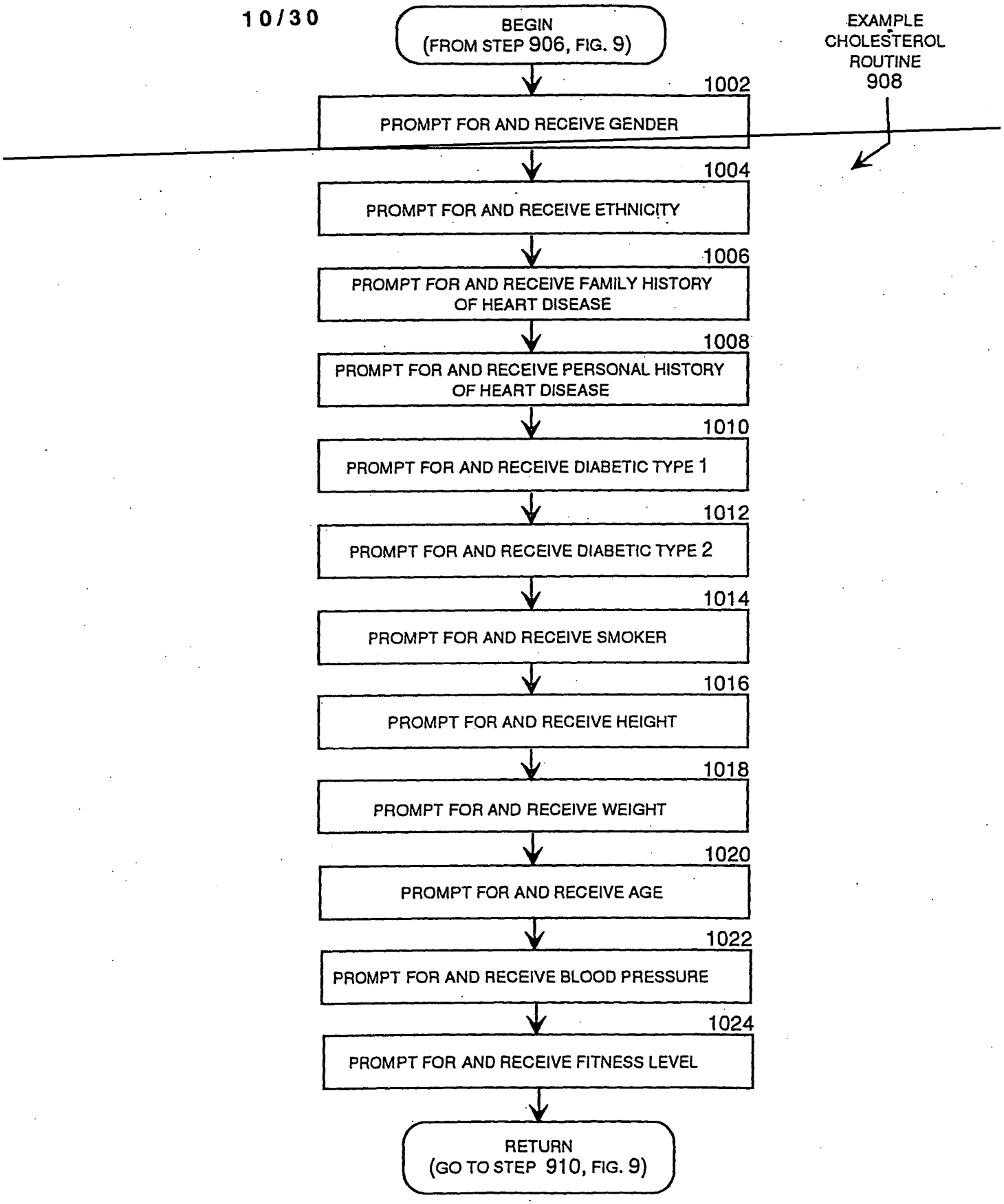

BEGIN
(FROM STEP 906, FIG. 9)
EXAMPLE CHOLESTEROL ROUTINE 908
1002
PROMPT FOR AND RECEIVE GENDER
1004
PROMPT FOR AND RECEIVE ETHNICITY
1006
PROMPT FOR AND RECEIVE FAMILY HISTORY OF HEART DISEASE
1008
PROMPT FOR AND RECEIVE PERSONAL HISTORY OF HEART DISEASE
1010
PROMPT FOR AND RECEIVE DIABETIC TYPE 1
1012
PROMPT FOR AND RECEIVE DIABETIC TYPE 2
1014
PROMPT FOR AND RECEIVE SMOKER
1016
PROMPT FOR AND RECEIVE HEIGHT
1018
PROMPT FOR AND RECEIVE WEIGHT
1020
PROMPT FOR AND RECEIVE AGE
1022
PROMPT FOR AND RECEIVE BLOOD PRESSURE
1024
PROMPT FOR AND RECEIVE FITNESS LEVEL
RETURN
(GO TO STEP 910, FIG. 9)

FIG. 10

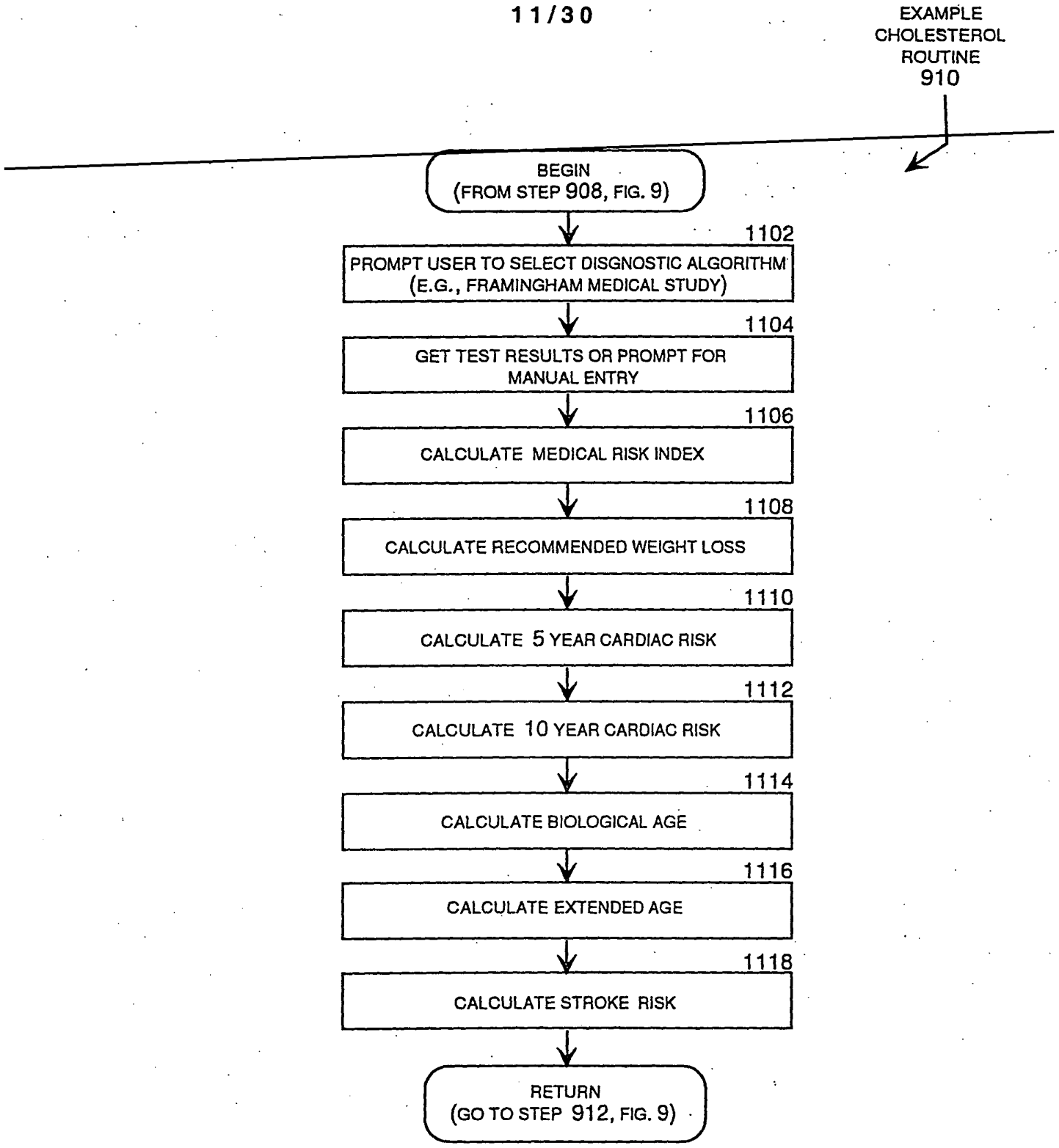

EXAMPLE CHOLESTEROL ROUTINE 910
BEGIN (FROM STEP 908, FIG. 9)
1102
PROMPT USER TO SELECT DISGNOSTIC ALGORITHM (E.G., FRAMINGHAM MEDICAL STUDY)
1104
GET TEST RESULTS OR PROMPT FOR MANUAL ENTRY
1106
CALCULATE MEDICAL RISK INDEX
1108
CALCULATE RECOMMENDED WEIGHT LOSS
1110
CALCULATE 5 YEAR CARDIAC RISK
1112
CALCULATE 10 YEAR CARDIAC RISK
1114
CALCULATE BIOLOGICAL AGE
1116
CALCULATE EXTENDED AGE
1118
CALCULATE STROKE RISK
RETURN (GO TO STEP 912, FIG. 9)

FIG. 11

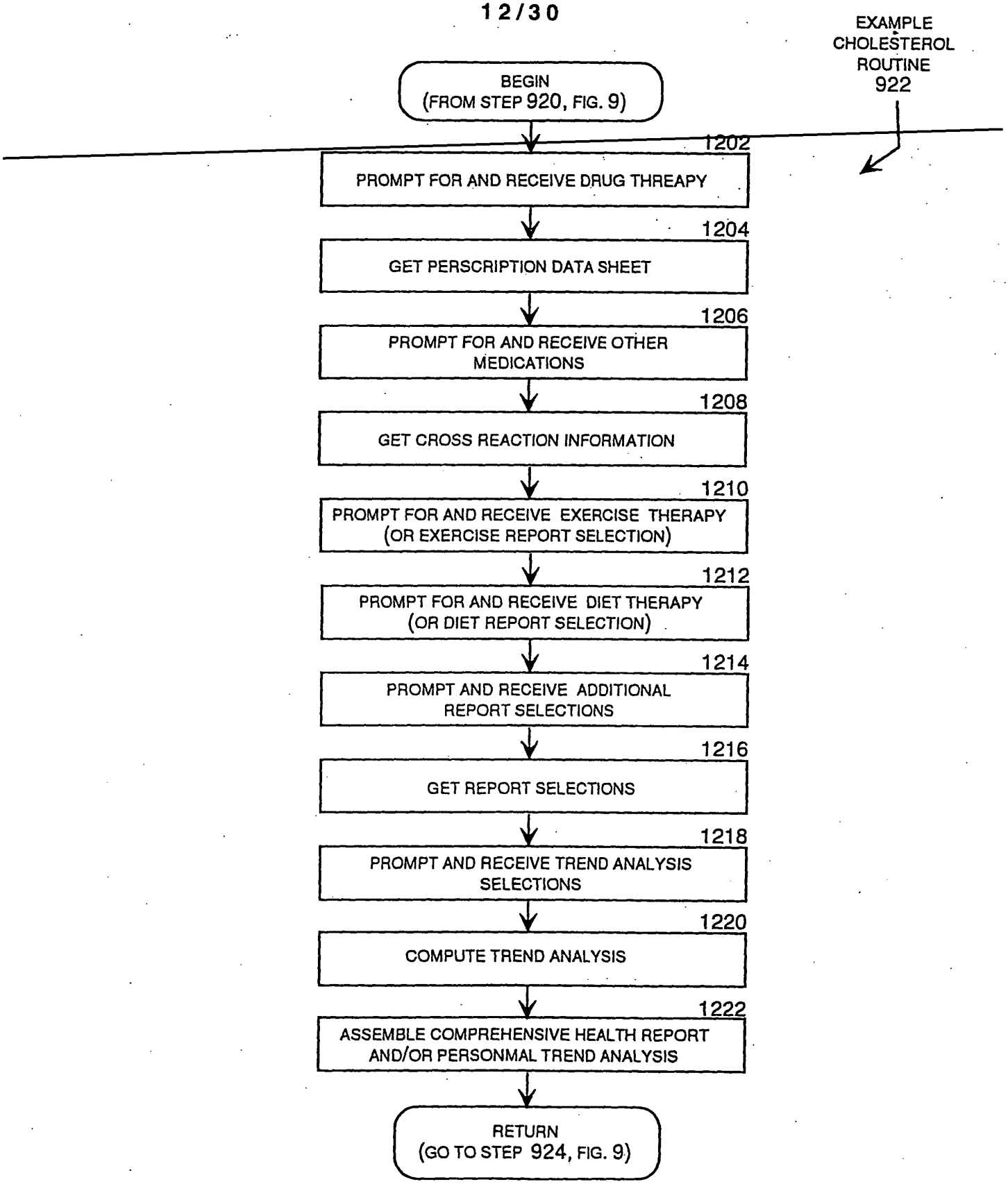

EXAMPLE CHOLESTEROL ROUTINE 922
BEGIN (FROM STEP 920, FIG. 9)
1202
PROMPT FOR AND RECEIVE DRUG THREAPY
1204
GET PERSCRIPTION DATA SHEET
1206
PROMPT FOR AND RECEIVE OTHER MEDICATIONS
1208
GET CROSS REACTION INFORMATION
1210
PROMPT FOR AND RECEIVE EXERCISE THERAPY (OR EXERCISE REPORT SELECTION)
1212
PROMPT FOR AND RECEIVE DIET THERAPY (OR DIET REPORT SELECTION)
1214
PROMPT AND RECEIVE ADDITIONAL REPORT SELECTIONS
1216
GET REPORT SELECTIONS
1218
PROMPT AND RECEIVE TREND ANALYSIS SELECTIONS
1220
COMPUTE TREND ANALYSIS
1222
ASSEMBLE COMPREHENSIVE HEALTH REPORT AND/OR PERSONMAL TREND ANALYSIS
RETURN (GO TO STEP 924, FIG. 9)

FIG. 12

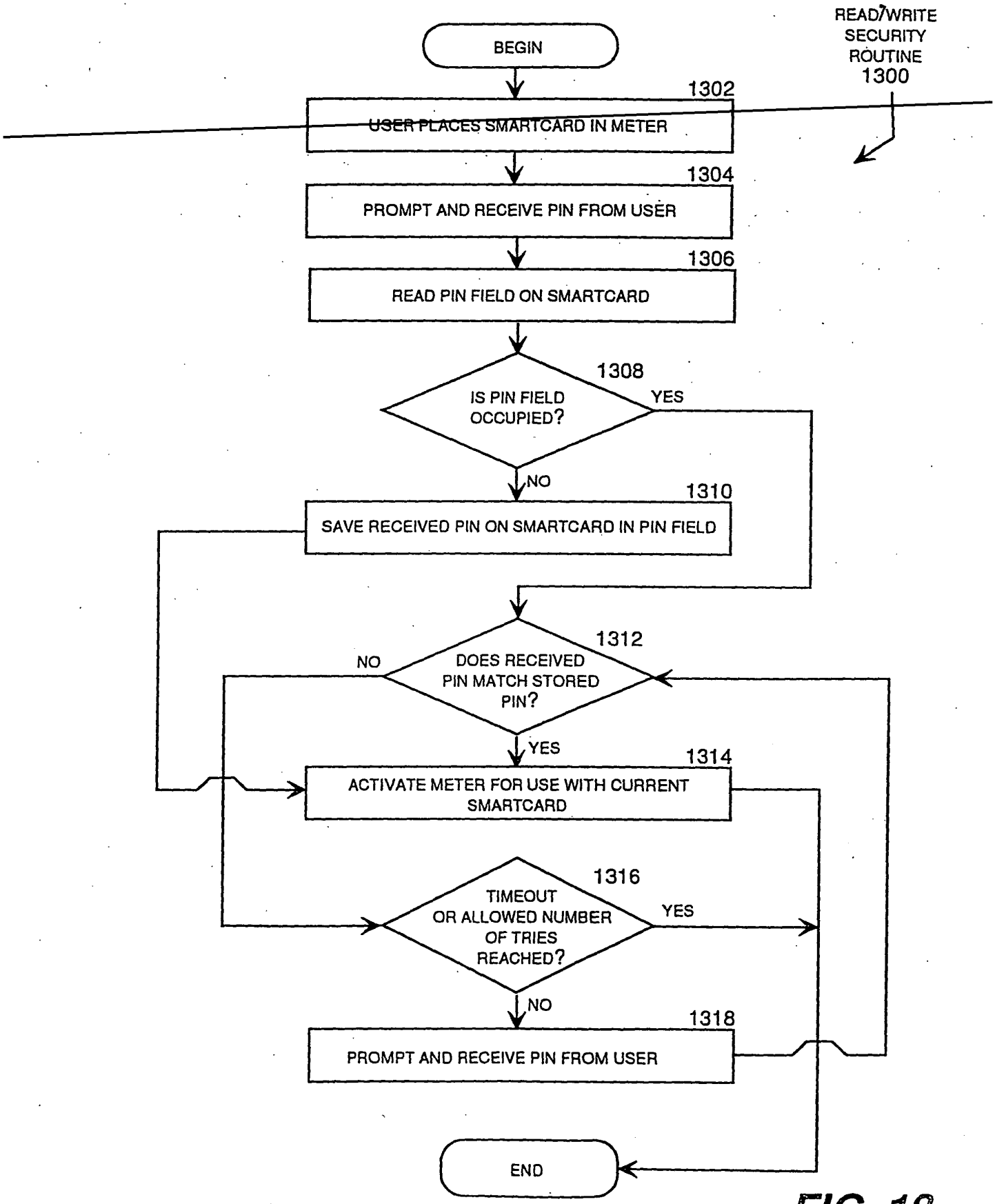

READ/WRITE SECURITY ROUTINE 1300
BEGIN
1302
USER PLACES SMARTCARD IN METER
1304
PROMPT AND RECEIVE PIN FROM USER
1306
READ PIN FIELD ON SMARTCARD
1308
IS PIN FIELD OCCUPIED?
YES
NO
1310
SAVE RECEIVED PIN ON SMARTCARD IN PIN FIELD
1312
DOES RECEIVED PIN MATCH STORED PIN?
NO
YES
1314
ACTIVATE METER FOR USE WITH CURRENT SMARTCARD
1316
TIMEOUT OR ALLOWED NUMBER OF TRIES REACHED?
YES
NO
1318
PROMPT AND RECEIVE PIN FROM USER
END

FIG. 13

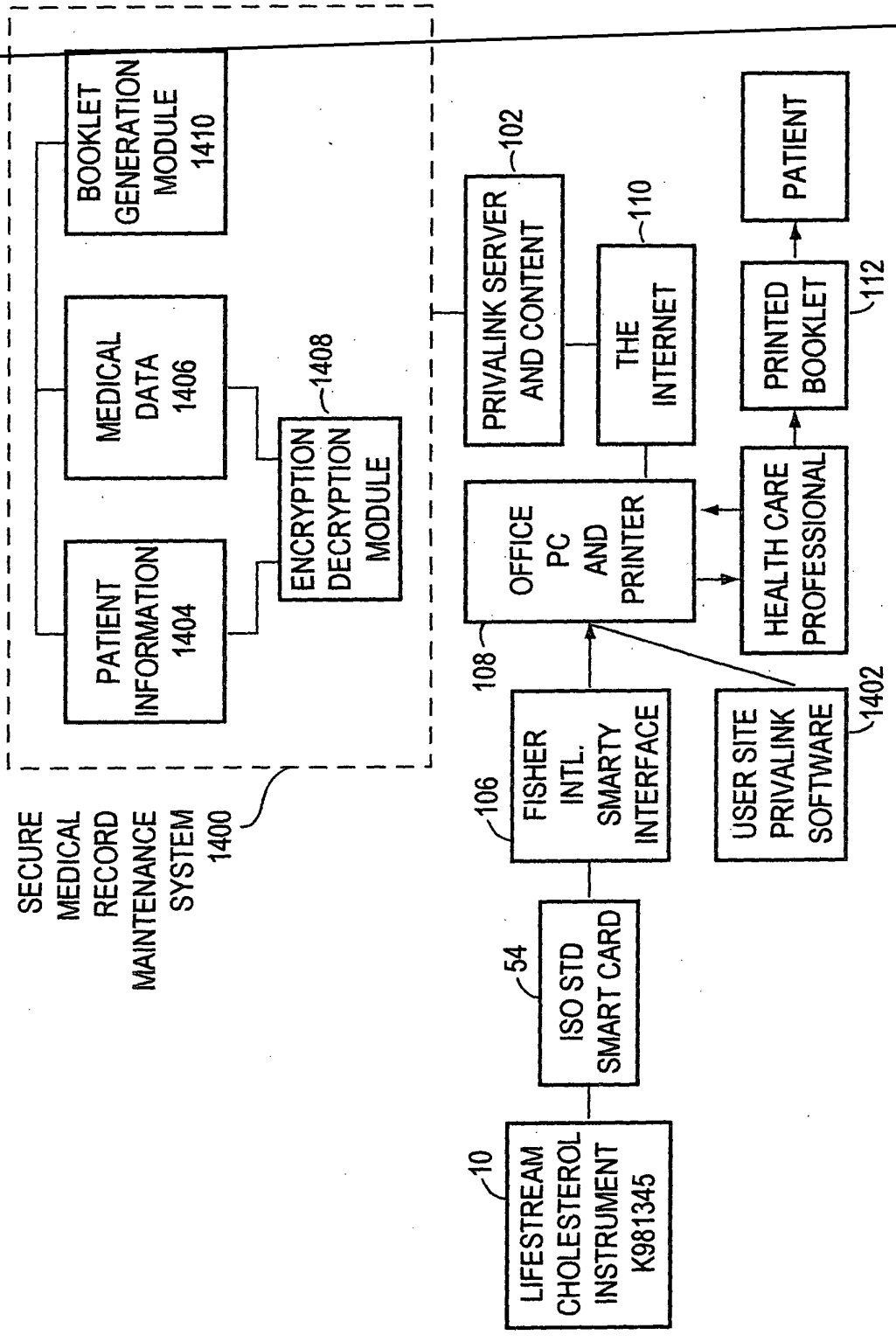

SECURE MEDICAL RECORD MAINTENANCE SYSTEM 1400
PATIENT INFORMATION 1404
MEDICAL DATA 1406
BOOKLET GENERATION MODULE 1410
ENCRYPTION DECRYPTION MODULE
1408
PRIVALINK SERVER AND CONTENT
102
THE INTERNET
110
PATIENT
PRINTED BOOKLET
112
OFFICE PC AND PRINTER
108
HEALTH CARE PROFESSIONAL
USER SITE PRIVALINK SOFTWARE
1402
FISHER INTL. SMARTY INTERFACE
106
ISO STD SMART CARD
54
LIFESTREAM CHOLESTEROL INSTRUMENT K981345
10

FIG. 14

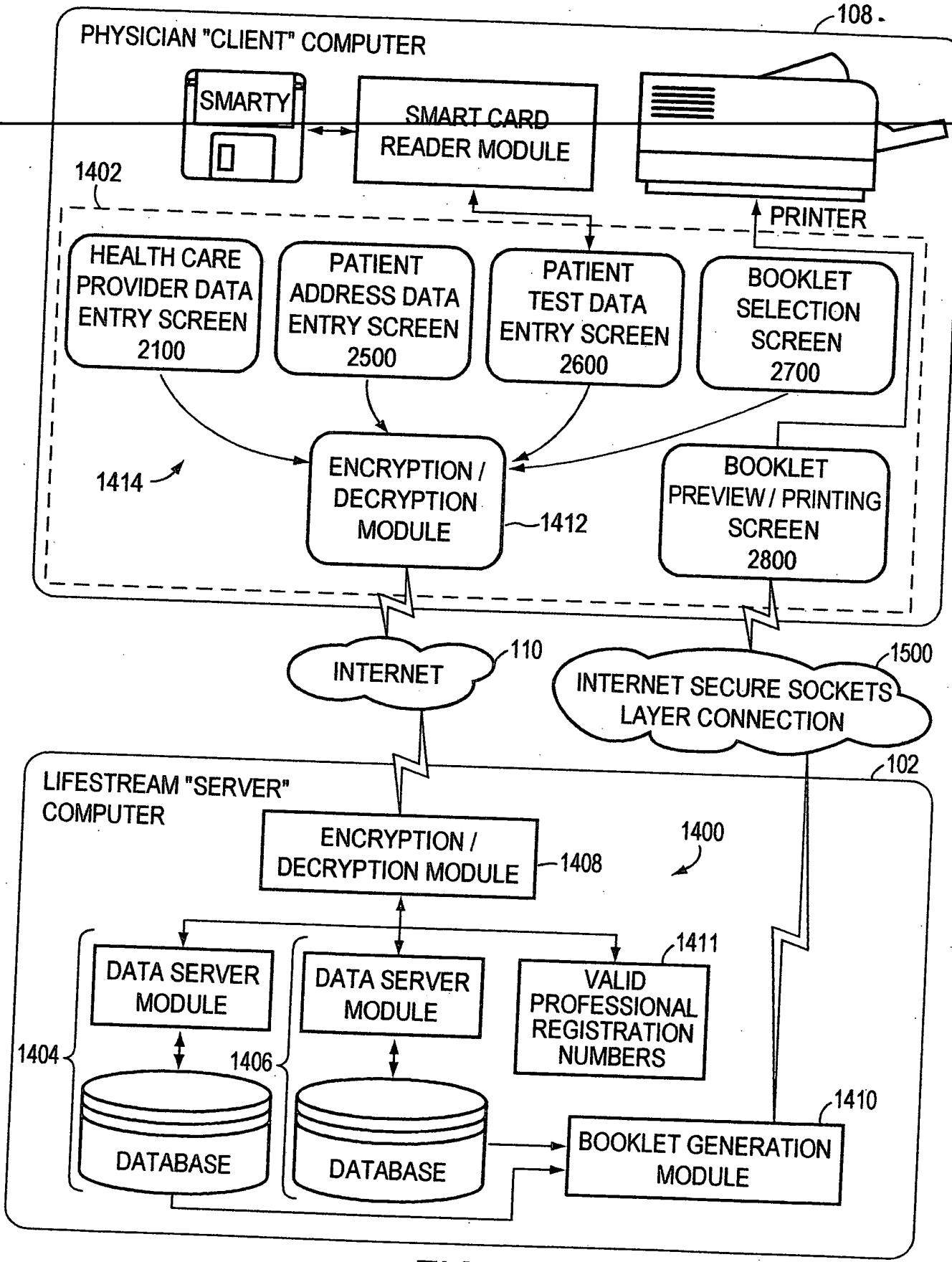

PHYSICIAN "CLIENT" COMPUTER
108
SMARTY
SMART CARD READER MODULE
PRINTER
1402
HEALTH CARE PROVIDER DATA ENTRY SCREEN 2100
PATIENT ADDRESS DATA ENTRY SCREEN 2500
PATIENT TEST DATA ENTRY SCREEN 2600
BOOKLET SELECTION SCREEN 2700
1414
ENCRYPTION / DECRYPTION MODULE
1412
BOOKLET PREVIEW / PRINTING SCREEN 2800
INTERNET
110
INTERNET SECURE SOCKETS LAYER CONNECTION
1500
LIFESTREAM "SERVER" COMPUTER
102
ENCRYPTION / DECRYPTION MODULE
1408
1400
DATA SERVER MODULE
DATA SERVER MODULE
VALID PROFESSIONAL REGISTRATION NUMBERS
1411
1404
1406
DATABASE
DATABASE
BOOKLET GENERATION MODULE
1410

FIG. 15

GLOBAL SYSTEM HARDWARE PICTORIAL

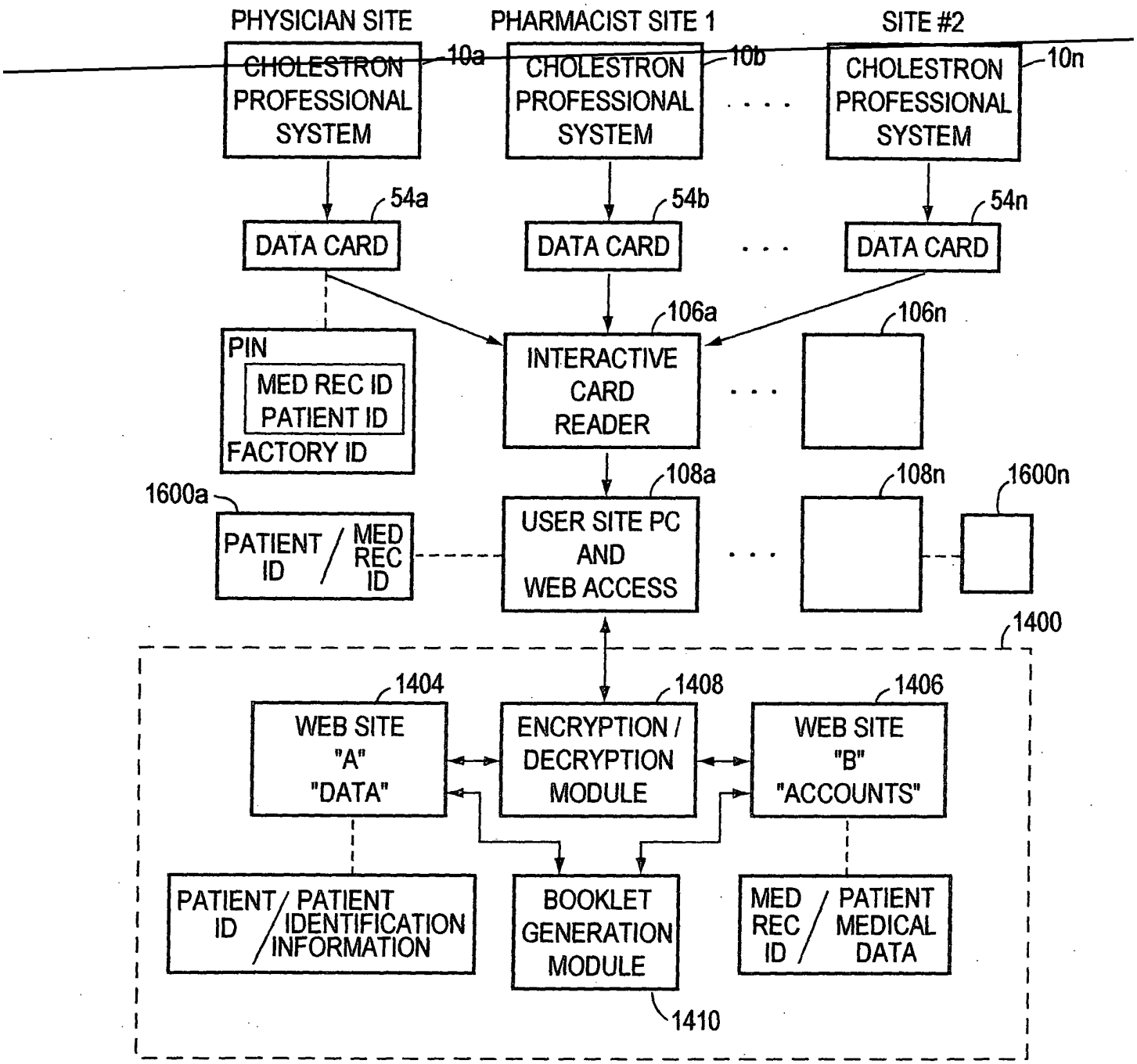


FIG. 16

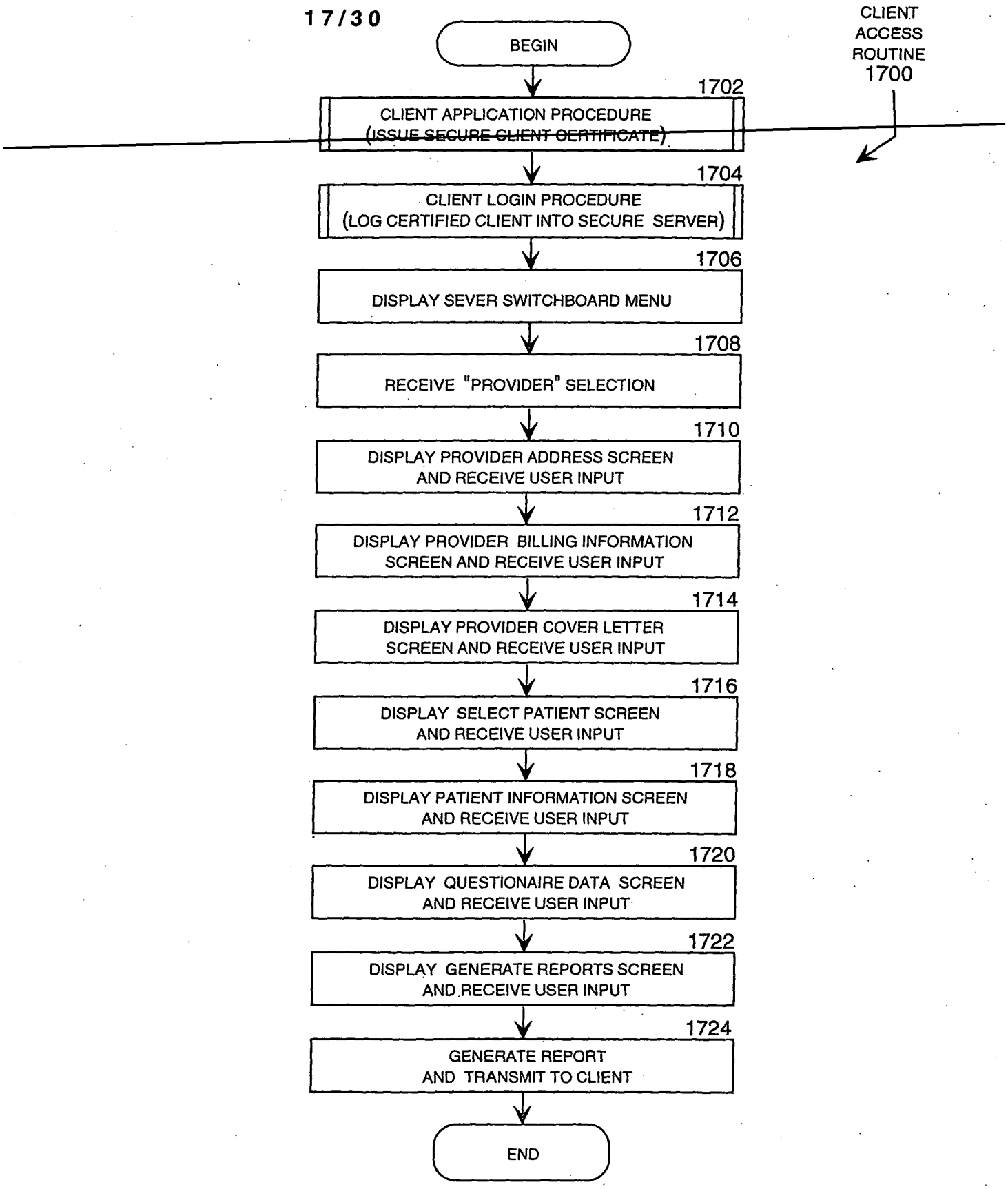

CLIENT ACCESS ROUTINE 1700
BEGIN
1702
CLIENT APPLICATION PROCEDURE (ISSUE SECURE CLIENT CERTIFICATE)
1704
CLIENT LOGIN PROCEDURE (LOG CERTIFIED CLIENT INTO SECURE SERVER)
1706
DISPLAY SEVER SWITCHBOARD MENU
1708
RECEIVE "PROVIDER" SELECTION
1710
DISPLAY PROVIDER ADDRESS SCREEN AND RECEIVE USER INPUT
1712
DISPLAY PROVIDER BILLING INFORMATION SCREEN AND RECEIVE USER INPUT
1714
DISPLAY PROVIDER COVER LETTER SCREEN AND RECEIVE USER INPUT
1716
DISPLAY SELECT PATIENT SCREEN AND RECEIVE USER INPUT
1718
DISPLAY PATIENT INFORMATION SCREEN AND RECEIVE USER INPUT
1720
DISPLAY QUESTIONAIRE DATA SCREEN AND RECEIVE USER INPUT
1722
DISPLAY GENERATE REPORTS SCREEN AND RECEIVE USER INPUT
1724
GENERATE REPORT AND TRANSMIT TO CLIENT
END

FIG. 17

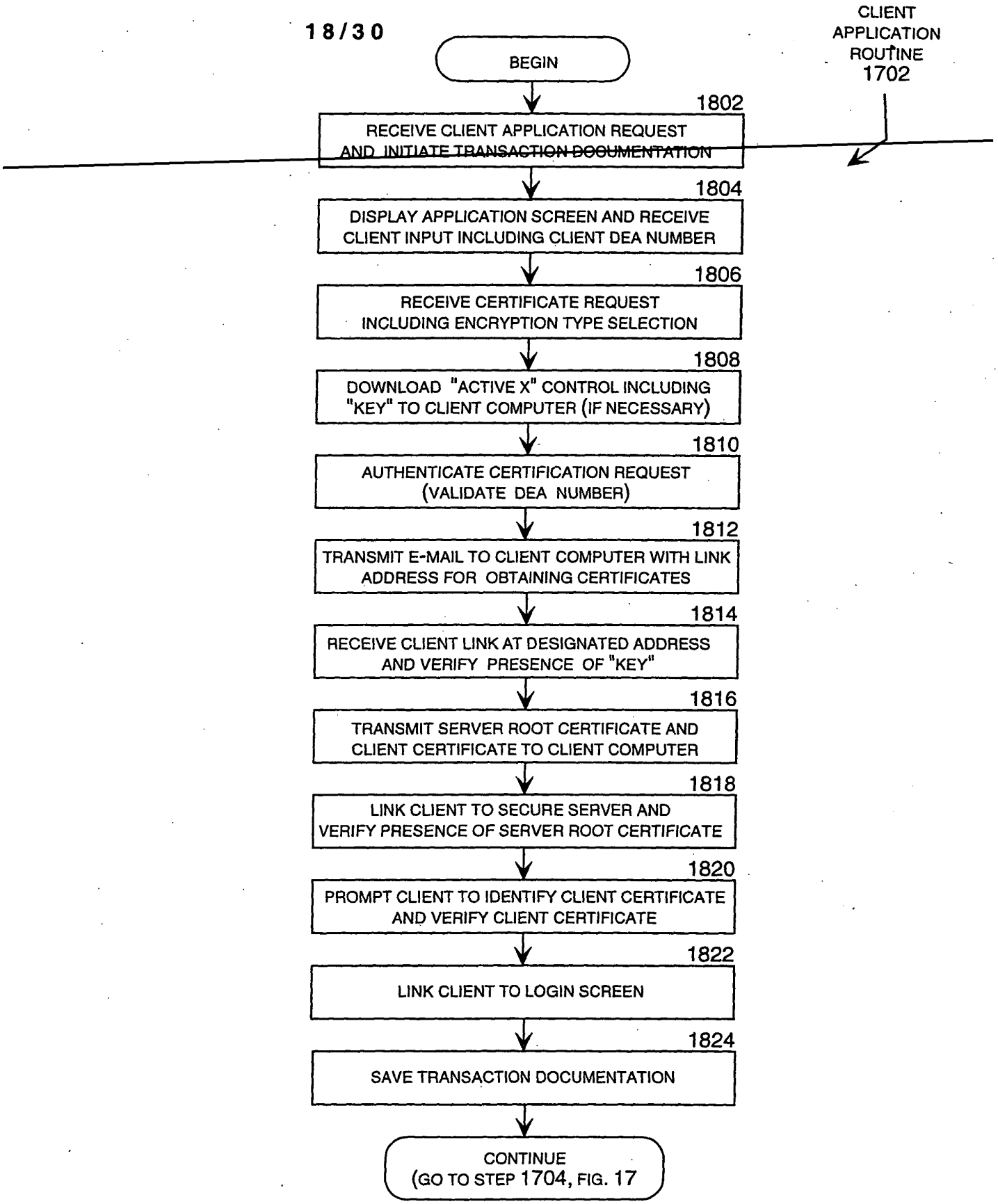

CLIENT APPLICATION ROUTINE 1702
BEGIN
1802
RECEIVE CLIENT APPLICATION REQUEST AND INITIATE TRANSACTION DOCUMENTATION
1804
DISPLAY APPLICATION SCREEN AND RECEIVE CLIENT INPUT INCLUDING CLIENT DEA NUMBER
1806
RECEIVE CERTIFICATE REQUEST INCLUDING ENCRYPTION TYPE SELECTION
1808
DOWNLOAD "ACTIVE X" CONTROL INCLUDING "KEY" TO CLIENT COMPUTER (IF NECESSARY)
1810
AUTHENTICATE CERTIFICATION REQUEST (VALIDATE DEA NUMBER)
1812
TRANSMIT E-MAIL TO CLIENT COMPUTER WITH LINK ADDRESS FOR OBTAINING CERTIFICATES
1814
RECEIVE CLIENT LINK AT DESIGNATED ADDRESS AND VERIFY PRESENCE OF "KEY"
1816
TRANSMIT SERVER ROOT CERTIFICATE AND CLIENT CERTIFICATE TO CLIENT COMPUTER
1818
LINK CLIENT TO SECURE SERVER AND VERIFY PRESENCE OF SERVER ROOT CERTIFICATE
1820
PROMPT CLIENT TO IDENTIFY CLIENT CERTIFICATE AND VERIFY CLIENT CERTIFICATE
1822
LINK CLIENT TO LOGIN SCREEN
1824
SAVE TRANSACTION DOCUMENTATION
CONTINUE (GO TO STEP 1704, FIG. 17

FIG. 18

CLIENT
LOGIN ROUTINE
1704

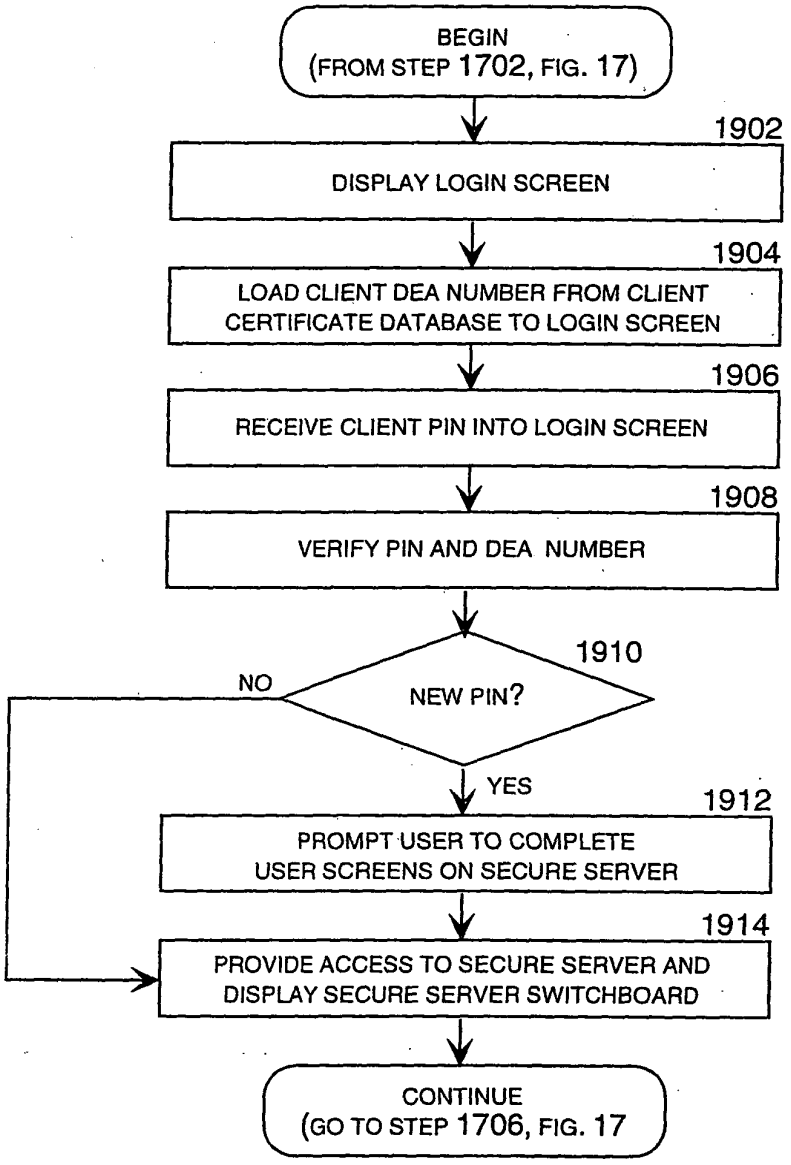


FIG. 19

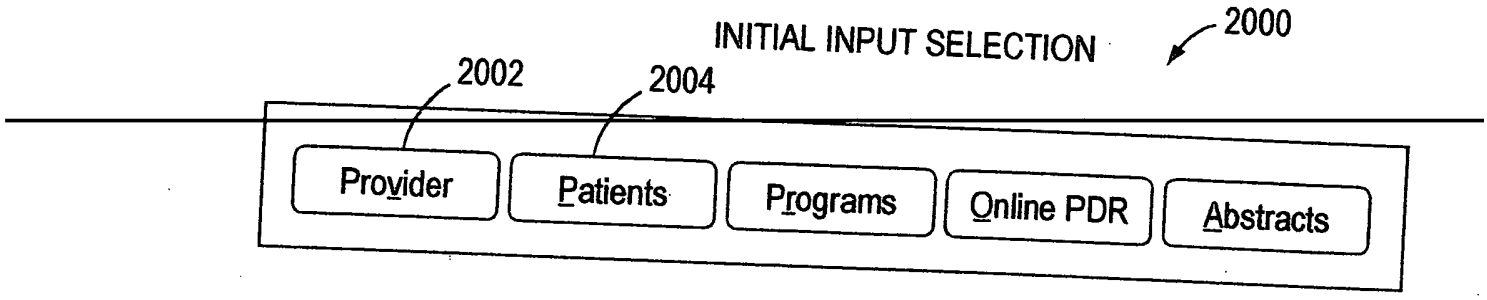

INITIAL INPUT SELECTION
2000
2002
2004
Provider
Patients
Programs
Online PDR
Abstracts

FIG. 20

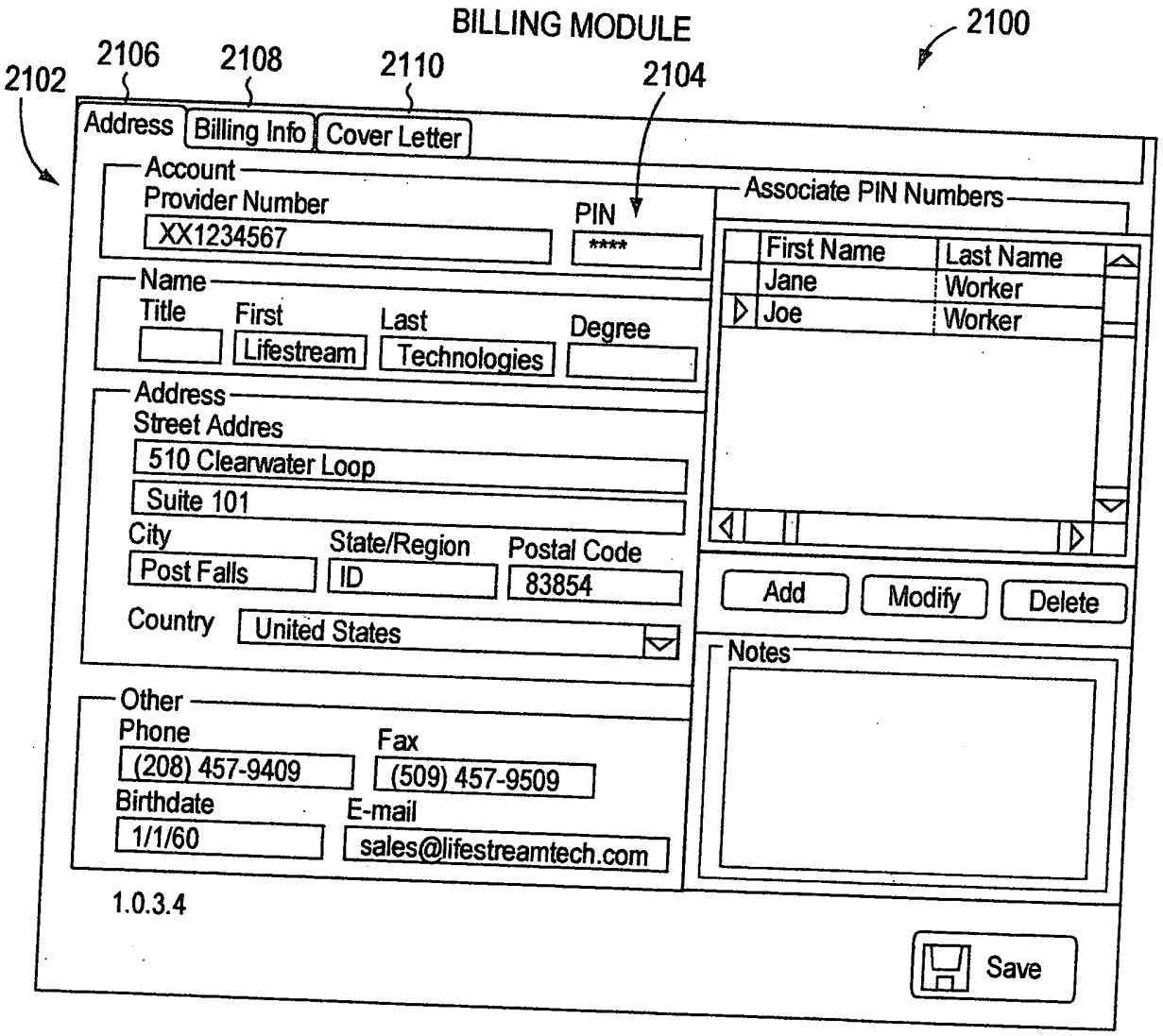

BILLING MODULE
2100
2102
2106
2108
2110
2104
Address
Billing Info
Cover Letter
Account
Provider Number
XX1234567
PIN
****
Associate PIN Numbers
First Name
Last Name
Jane
Worker
Joe
Worker
Name
Title
First
Lifestream
Last
Technologies
Degree
Address
Street Addres
510 Clearwater Loop
Suite 101
City
Post Falls
State/Region
ID
Postal Code
83854
Country
United States
Add
Modify
Delete
Notes
Other
Phone
(208) 457-9409
Fax
(509) 457-9509
Birthdate
1/1/60
E-mail
sales@lifestreamtech.com
1.0.3.4
Save

FIG. 21

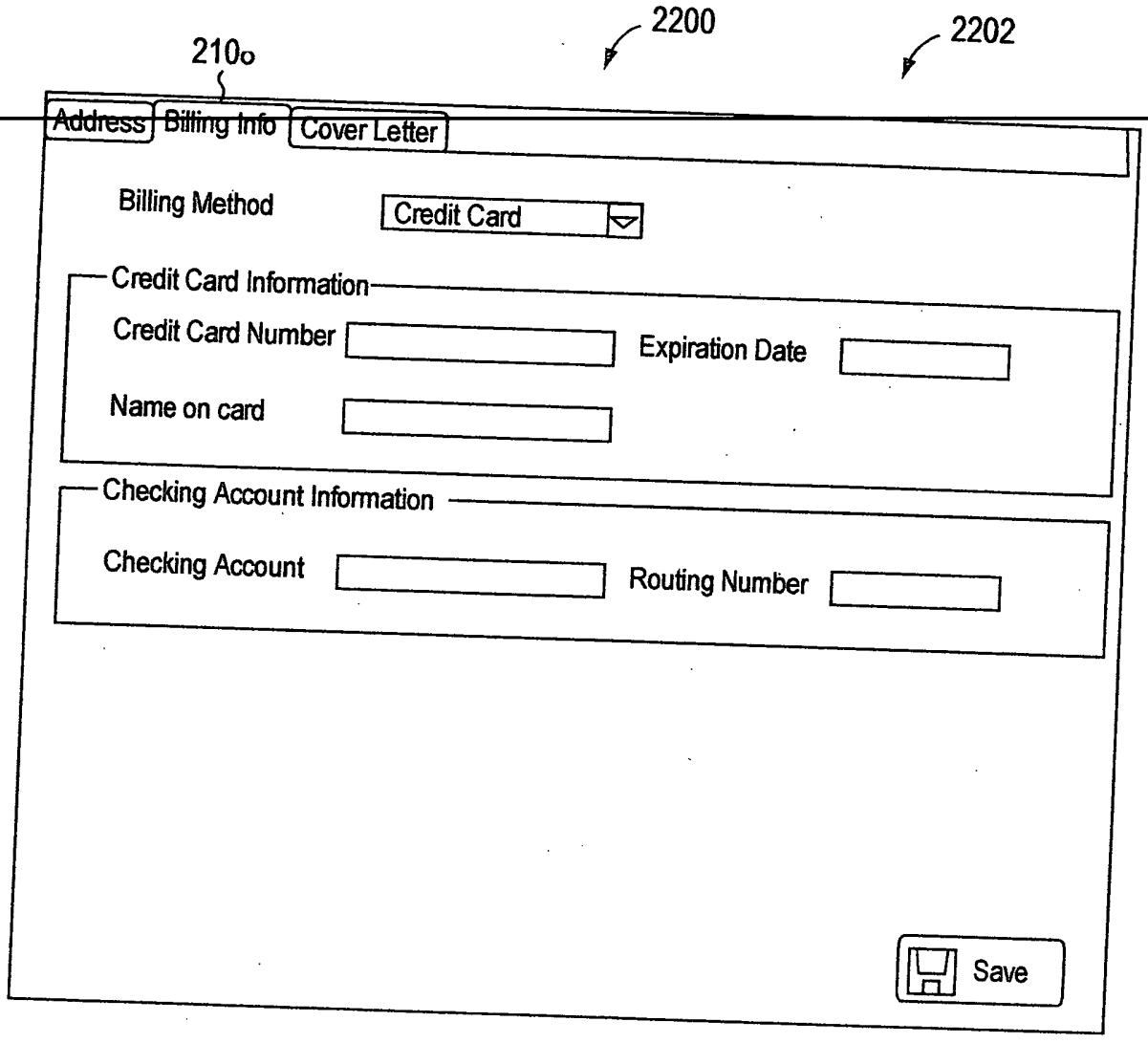

2200
2202
210o
Address
Billing Info
Cover Letter
Billing Method
Credit Card
Credit Card Information
Credit Card Number
Expiration Date
Name on card
Checking Account Information
Checking Account
Routing Number
Save

FIG. 22

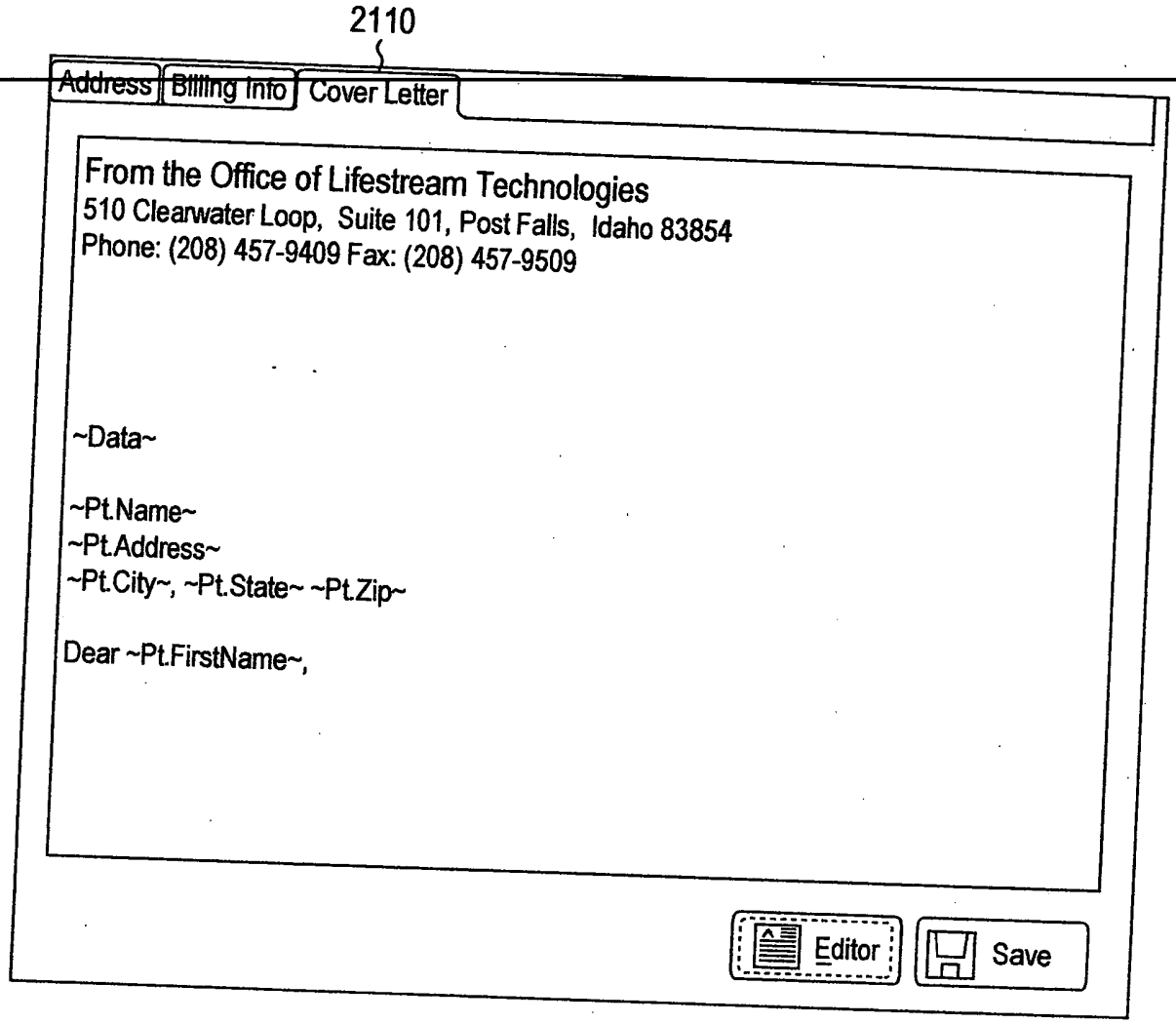

2110
Address
Billing Info
Cover Letter
From the Office of Lifestream Technologies
510 Clearwater Loop, Suite 101, Post Falls, Idaho 83854
Phone: (208) 457-9409 Fax: (208) 457-9509
~Data~
~Pt.Name~
~Pt.Address~
~Pt.City~, ~Pt.State~ ~Pt.Zip~
Dear ~Pt.FirstName~,
Editor
Save

FIG. 23

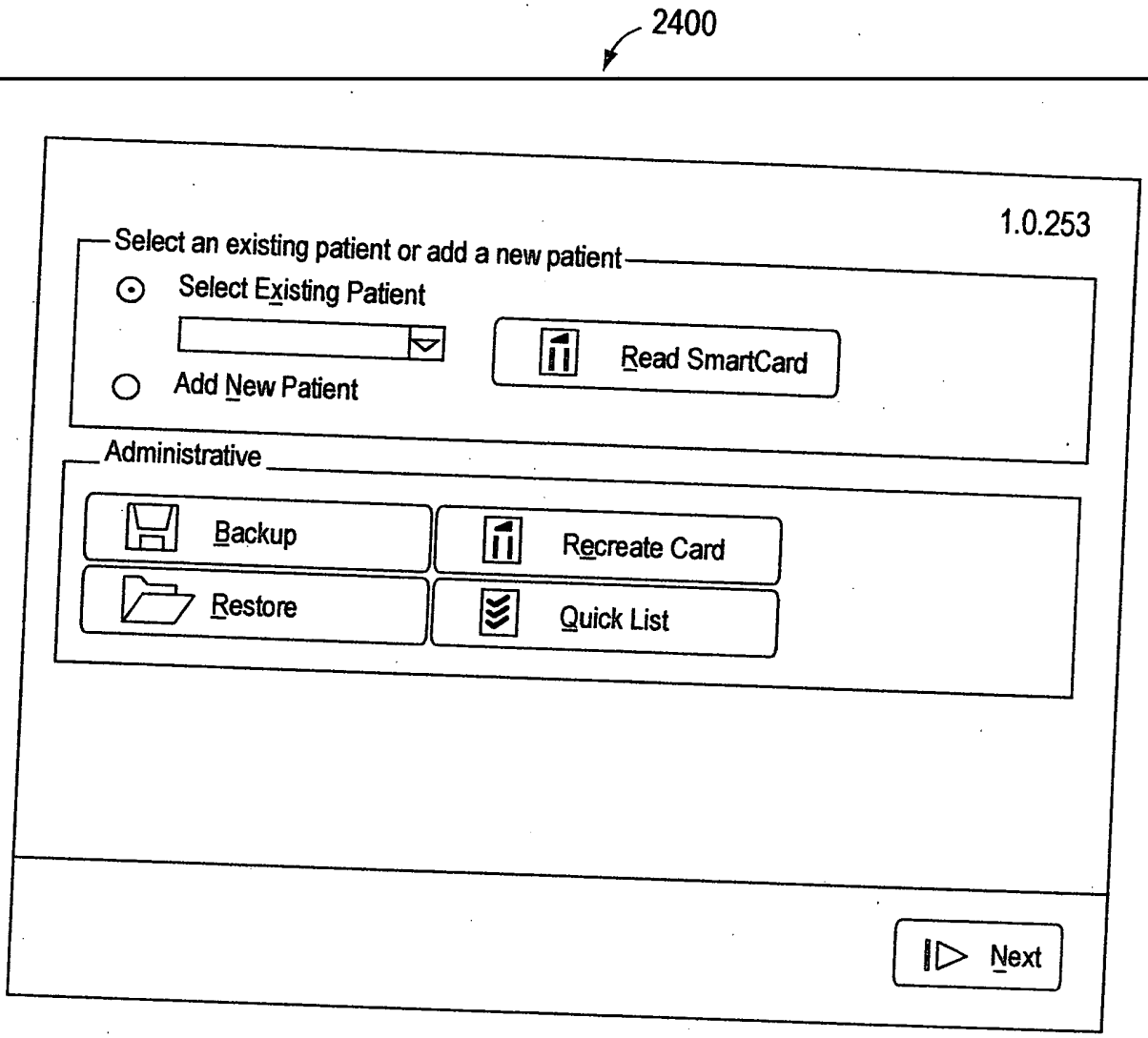

2400
1.0.253
Select an existing patient or add a new patient
Select Existing Patient
Add New Patient
Read SmartCard
Administrative
Backup
Recreate Card
Restore
Quick List
Next

FIG. 24

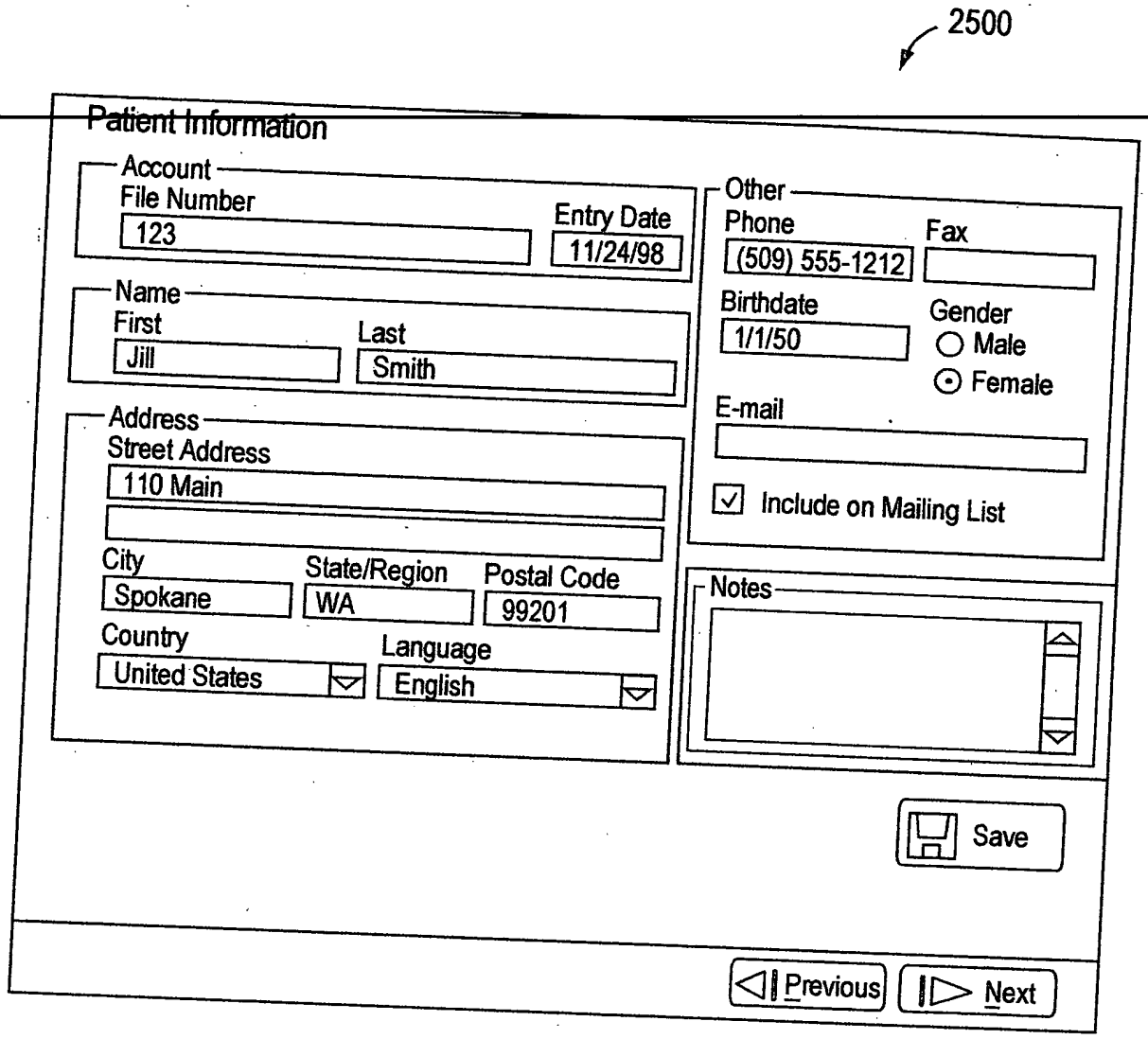

2500
Patient Information
Account
File Number
123
Entry Date
11/24/98
Name
First
Jill
Last
Smith
Address
Street Address
110 Main
City
Spokane
State/Region
WA
Postal Code
99201
Country
United States
Language
English
Other
Phone
(509) 555-1212
Fax
Birthdate
1/1/50
Gender
Male
Female
E-mail
Include on Mailing List
Notes
Save
Previous
Next

FIG. 25

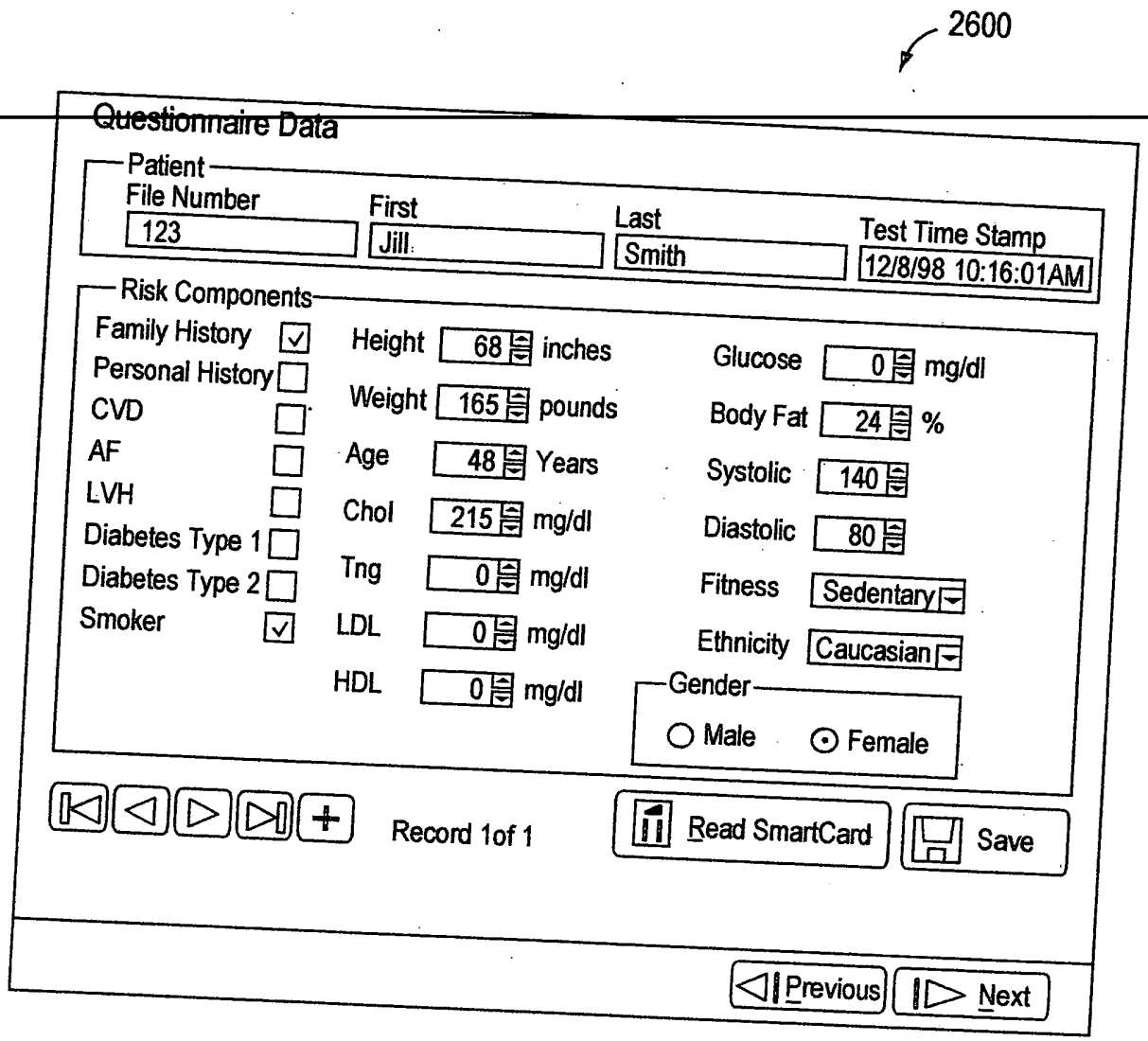

2600
Questionnaire Data
Patient
File Number
123
First
Jill
Last
Smith
Test Time Stamp
12/8/98 10:16:01AM
Risk Components
Family History
Personal History
CVD
AF
LVH
Diabetes Type 1
Diabetes Type 2
Smoker
Height 68 inches
Weight 165 pounds
Age 48 Years
Chol 215 mg/dl
Tng 0 mg/dl
LDL 0 mg/dl
HDL 0 mg/dl
Glucose 0 mg/dl
Body Fat 24 %
Systolic 140
Diastolic 80
Fitness Sedentary
Ethnicity Caucasian
Gender
Male
Female
Record 1of 1
Read SmartCard
Save
Previous
Next

FIG. 26

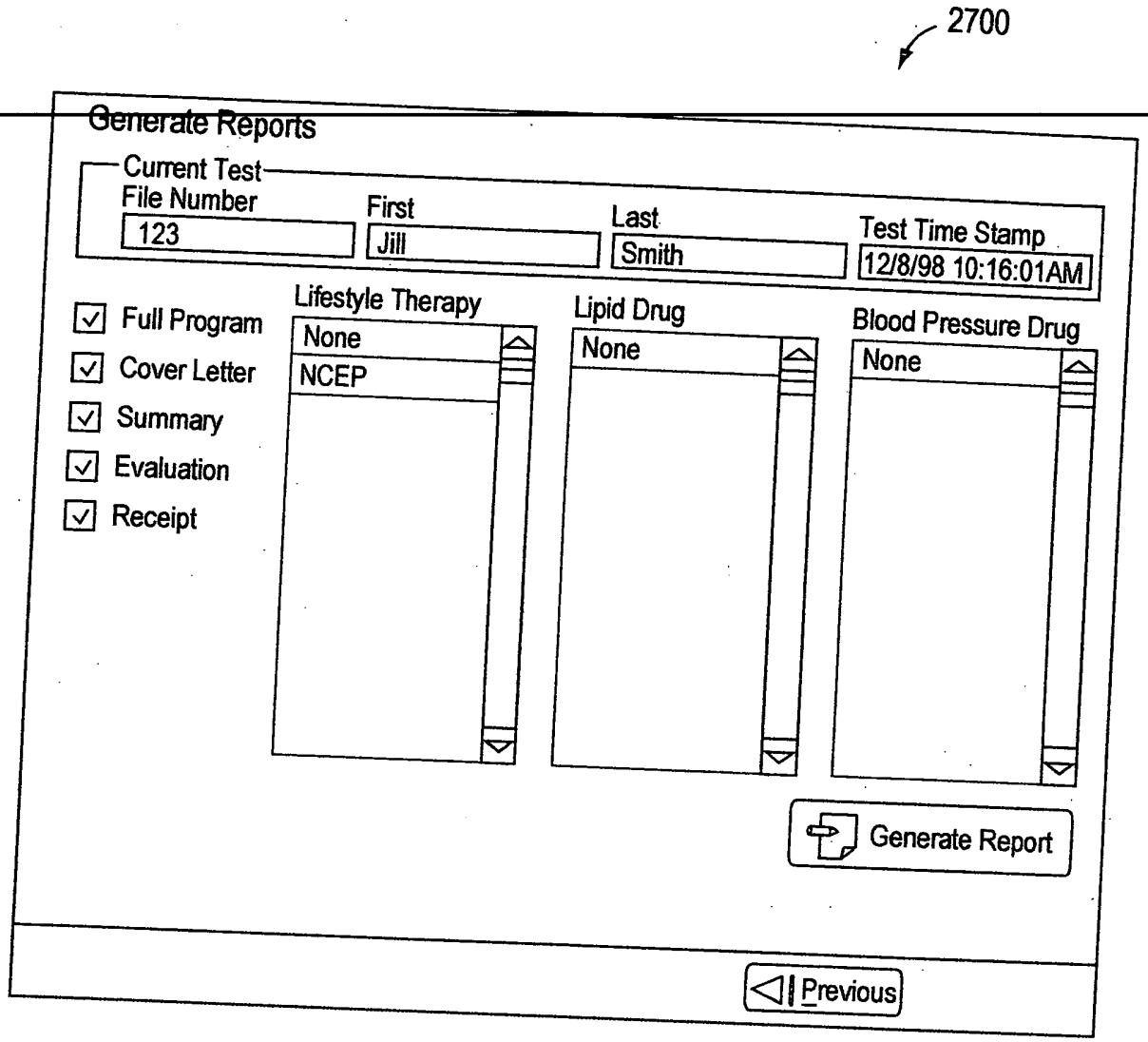

2700
Generate Reports
Current Test
File Number
123
First
Jill
Last
Smith
Test Time Stamp
12/8/98 10:16:01AM
Full Program
Cover Letter
Summary
Evaluation
Receipt
Lifestyle Therapy
None
NCEP
Lipid Drug
None
Blood Pressure Drug
None
Generate Report
Previous

FIG. 27

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	CORONARY RISK FACTORS	TEST RESULTS	IDEAL RANGE	GOALS
	GENDER	MALE		
IDEAL	PERSONAL HISTORY	NO	NONE	
IDEAL	FAMILY HISTORY	NO	NONE	
	CVD	NO		
	AF	NO		
	LVH	NO		
MODERATE	DIABETES (TYPE 1)	YES	NONE	
HIGH	SMOKER	YES	NO	
	HEIGHT	66 in		
	WEIGHT	155 lbs		
	AGE	44		
MODERATE	TOTAL CHOLESTEROL	211	< 200	
	TRIGLYCERIDES	200		
	HDL	N/A	45-65	
	LDL	N/A	65-135	
	GLUCOSE	N/A		
IDEAL	PERCENTAGE OF BODY FAT	N/A	18%	
IDEAL	BP SYSTOLIC	115	< 120	
LOW	BP DIASTOLIC	80	< 80	
LOW	FITNESS	MODERATE	HIGH	

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PERSONAL HEALTH CONSEQUENCES		
BODY MASS INDEX (BMI)	25	< 25
POUNDS OVERWEIGHT	0	0
CHOLESTEROL/HDL RATIO	N/A:1	< 3.5:1
CARDIAC RISK	5 YEARS - 5% 10 YEARS - 10%	
BIOLOGICAL AGE	47	< 44
STROKE RISK	10 YEARS - LOW RISK	

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EXTENDED HEALTH ASSESSMENT SUMMARY

CHRONOLOGICAL AGE	30	40	50	60	70
CARDIAC AGE	N/A	N/A	52	62	69

FIG. 28

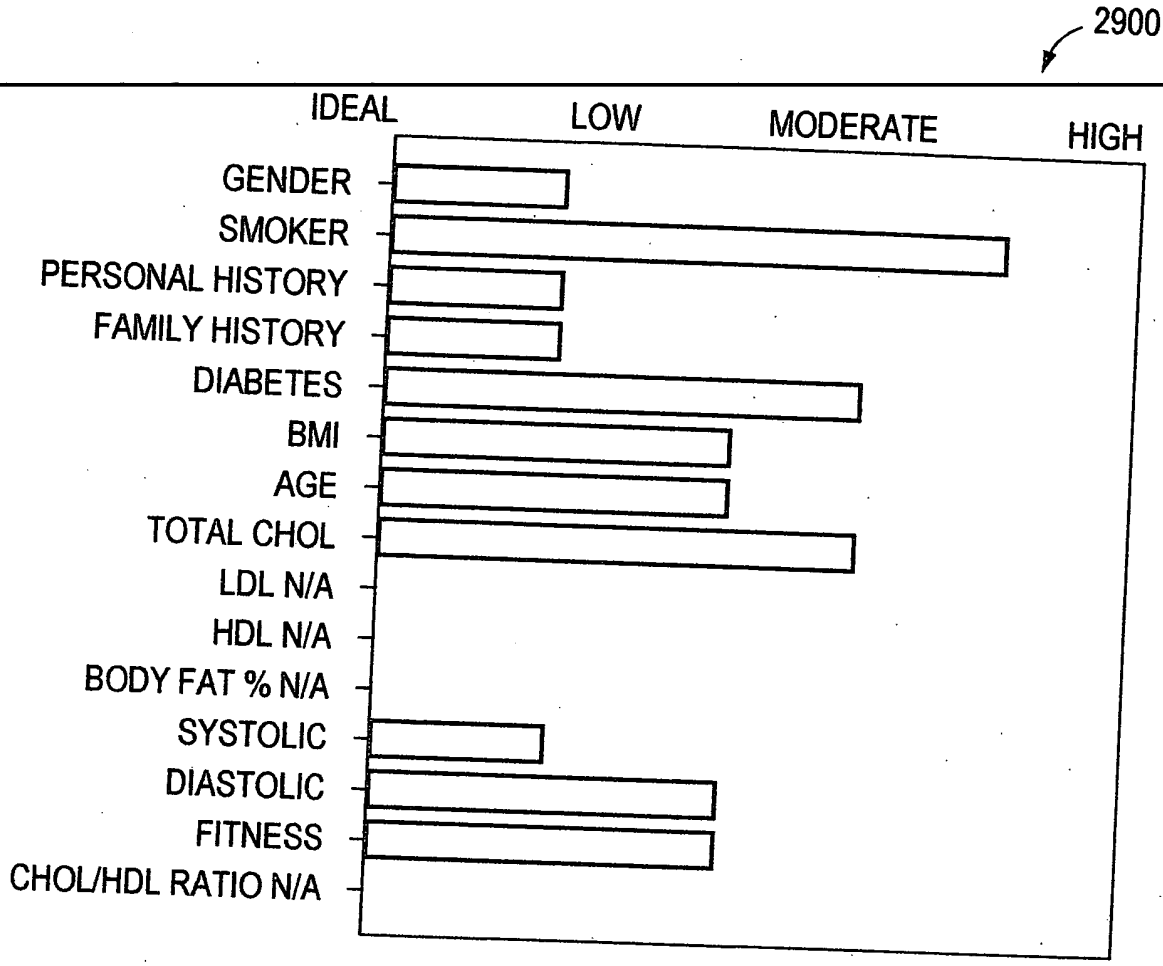
2900
IDEAL
LOW
MODERATE
HIGH
GENDER
SMOKER
PERSONAL HISTORY
FAMILY HISTORY
DIABETES
BMI
AGE
TOTAL CHOL
LDL N/A
HDL N/A
BODY FAT % N/A
SYSTOLIC
DIASTOLIC
FITNESS
CHOL/HDL RATIO N/A

FIG. 29

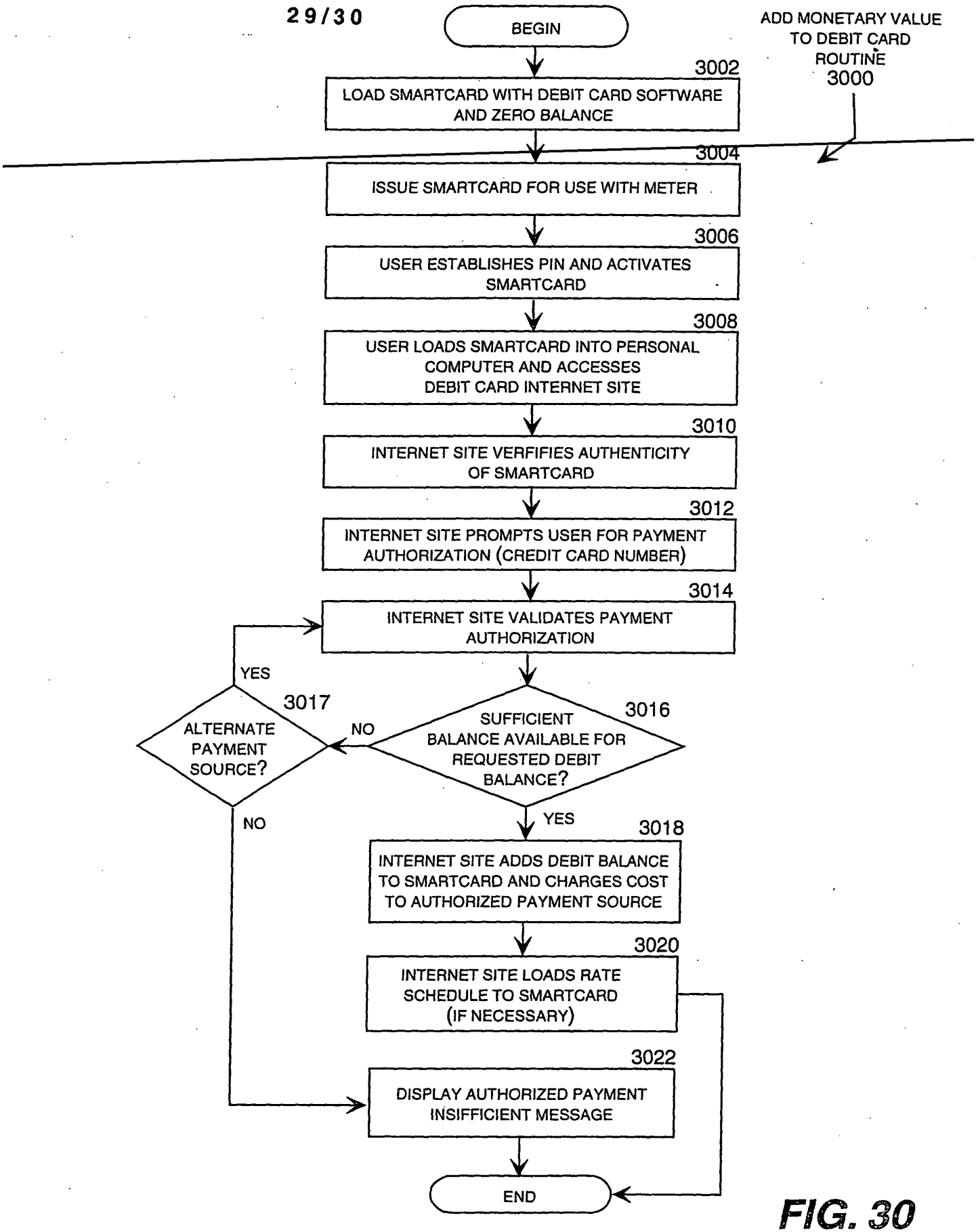
BEGIN
ADD MONETARY VALUE TO DEBIT CARD ROUTINE
3000
3002
LOAD SMARTCARD WITH DEBIT CARD SOFTWARE AND ZERO BALANCE
3004
ISSUE SMARTCARD FOR USE WITH METER
3006
USER ESTABLISHES PIN AND ACTIVATES SMARTCARD
3008
USER LOADS SMARTCARD INTO PERSONAL COMPUTER AND ACCESSES DEBIT CARD INTERNET SITE
3010
INTERNET SITE VERFIFIES AUTHENTICITY OF SMARTCARD
3012
INTERNET SITE PROMPTS USER FOR PAYMENT AUTHORIZATION (CREDIT CARD NUMBER)
3014
INTERNET SITE VALIDATES PAYMENT AUTHORIZATION
3016
SUFFICIENT BALANCE AVAILABLE FOR REQUESTED DEBIT BALANCE?
NO
3017
ALTERNATE PAYMENT SOURCE?
YES
NO
YES
3018
INTERNET SITE ADDS DEBIT BALANCE TO SMARTCARD AND CHARGES COST TO AUTHORIZED PAYMENT SOURCE
3020
INTERNET SITE LOADS RATE SCHEDULE TO SMARTCARD (IF NECESSARY)
3022
DISPLAY AUTHORIZED PAYMENT INSIFFICIENT MESSAGE
END

FIG. 30

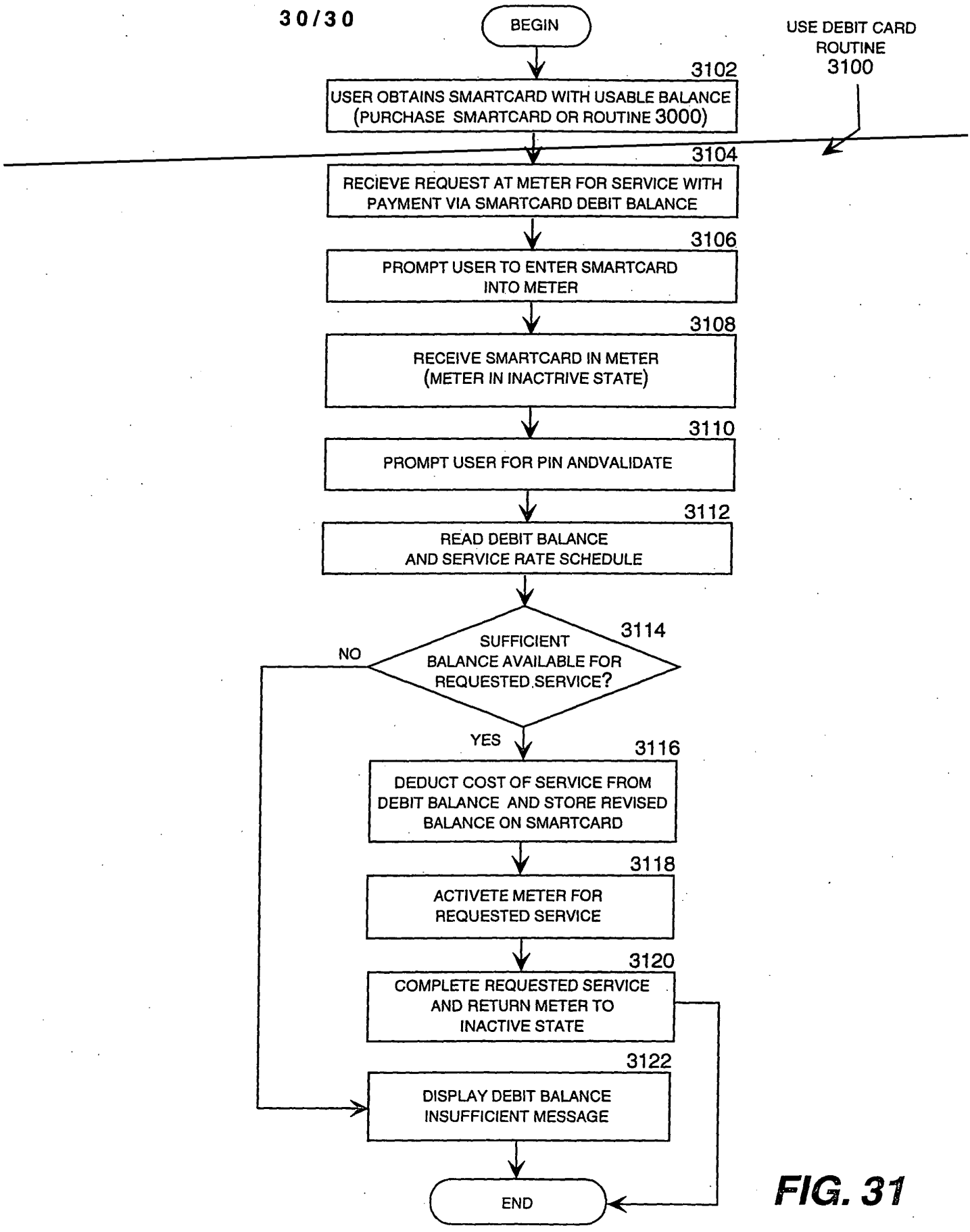
BEGIN
USE DEBIT CARD ROUTINE 3100
3102
USER OBTAINS SMARTCARD WITH USABLE BALANCE (PURCHASE SMARTCARD OR ROUTINE 3000)
3104
RECIEVE REQUEST AT METER FOR SERVICE WITH PAYMENT VIA SMARTCARD DEBIT BALANCE
3106
PROMPT USER TO ENTER SMARTCARD INTO METER
3108
RECEIVE SMARTCARD IN METER (METER IN INACTRIVE STATE)
3110
PROMPT USER FOR PIN ANDVALIDATE
3112
READ DEBIT BALANCE AND SERVICE RATE SCHEDULE
3114
SUFFICIENT BALANCE AVAILABLE FOR REQUESTED SERVICE?
NO
YES
3116
DEDUCT COST OF SERVICE FROM DEBIT BALANCE AND STORE REVISED BALANCE ON SMARTCARD
3118
ACTIVETE METER FOR REQUESTED SERVICE
3120
COMPLETE REQUESTED SERVICE AND RETURN METER TO INACTIVE STATE
3122
DISPLAY DEBIT BALANCE INSUFFICIENT MESSAGE
END

FIG. 31